

IN THE UNITED STATES DISTRICT COURT  
FOR THE WESTERN DISTRICT OF LOUISIANA  
MONROE DIVISION

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STATE OF LOUISIANA, *et al.*,

Plaintiffs,

v.

XAVIER BECERRA, in his official capacity  
as Secretary of the United States Department  
of Health and Human Services, *et al.*,

Defendants.

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Civil Action No. 3:21-CV-04370-TAD-KDM

**DEFENDANTS' RESPONSE IN OPPOSITION TO  
PLAINTIFFS' MOTION FOR TEMPORARY RESTRAINING ORDER  
AND PRELIMINARY INJUNCTION**

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## INTRODUCTION

A deadly disease called COVID-19 has ravaged the nation. By the time the rule at issue here was published a month ago, SARS-CoV-2, the virus that causes COVID-19, had infected over 50 million people and claimed more than 800,000 lives in the United States. Those numbers continue to grow. *See* Centers for Disease Control and Prevention (“CDC”), COVID Data Tracker Weekly Review (Dec. 17, 2021), <https://perma.cc/JWM5-5SZ4>. The highly transmissible virus can easily pass from person to person. As a result, the pandemic has been devastating for children and families alike. Fortunately, safe and effective vaccines are now approved or authorized for emergency use to protect against COVID-19.

The Secretary of Health and Human Services (the “Secretary”) reviewed the evidence and concluded that he must take urgent action to protect Head Start students and those interacting with them from infection. Head Start, a federal grant program, provides funding to aid school readiness for infants, toddlers, and pre-school aged children from low-income families. The COVID-19 pandemic has hit Head Start students and families particularly hard. Head Start students are under five, and thus cannot be vaccinated. Many of these students rely on the programs not just for educational purposes, but also for everyday needs such as meals, so program closures due to COVID-19 outbreaks have severe negative consequences beyond the classroom. In addition, a majority of Head Start children and personnel come from minority and low-income communities, which have been disproportionately impacted by COVID-19.

Congress has assigned the Secretary a statutory responsibility to protect the health and safety of Head Start students and personnel. To do so, the Secretary issued an Interim Final Rule, Vaccine and Mask Requirements to Mitigate the Spread of COVID-19 in Head Start Programs, 86 Fed. Reg. 68,052 (Nov. 30, 2021) (the “Rule”), requiring that those interacting with Head Start students be vaccinated for COVID-19, or otherwise qualify for an exemption. These individuals are required to receive a single-shot vaccine or to obtain the second shot of a two-dose vaccine by January 31, 2022, or to request an exemption from this requirement from their employer. The Rule also requires

masking, effective immediately, for all Head Start students over two years old and those Head Start personnel who have contact with students. The Secretary issued the Rule on an emergency basis, and waived a comment period in advance of publication (though the comment period is currently open until December 30, 2021), because there was an imminent need to protect children against a spike in COVID-19 cases in the winter months. The Rule also anticipates the Office of Head Start's planned return to fully in-person services in January 2022. The Rule is therefore necessary to avoid further disruption to Head Start children's development and learning.

Plaintiffs, a collection of twenty-four states, seek a preliminary injunction or temporary restraining order to prevent the Secretary from enforcing the Rule. As an initial matter, Plaintiffs—which do not directly receive Head Start funds to operate classrooms under 42 U.S.C. § 9836—lack standing to pursue their claims. Moreover, they have not demonstrated that they are entitled to this extraordinary remedy. Most importantly, they are unlikely to succeed on the merits. The Secretary has express statutory authority to ensure that federal funds are used to protect the health and safety of Head Start students and personnel. He has exercised this authority for decades, including by promulgating regulations requiring Head Start participants to receive a slate of vaccinations, *see, e.g.*, 45 C.F.R. § 1304.3-4(2) (1975), and requiring staff to undergo health examinations and screenings, *see, e.g.*, Head Start Program, 61 Fed. Reg. 57,186, 57,210, 57,223 (Nov. 5, 1996). Similarly, here, the Secretary reasonably exercised that authority to arrive at the vaccination and mask Rule. He explained that the need to protect the health and safety of those in the Head Start program compelled him to act now. The Secretary accordingly took emergency measures to protect the health and safety of children in the coming weeks and months and to preserve their ability to access the critical resources that Head Start programs provide.

Plaintiffs also cannot meet their burden to demonstrate the remaining preliminary injunction factors. A regulation that amends the requirements for a discretionary grant awarded primarily to localities cannot cause irreparable harm to Plaintiffs' sovereign interests. And any other alleged harm



to Head Start programs from staff departure is entirely speculative. The equities and public interest also weigh heavily against an injunction, which would undermine the public's significant interest in protecting the health of children and preserving their ability to obtain an education and receive the many other benefits that Head Start programs provide.

Finally, in the event that this Court decides to order some relief, it should extend no more broadly than the Head Start programs operated by any Plaintiffs that the Court concludes have standing. More sweeping relief is uncalled for and contrary to binding Fifth Circuit precedent. *See Louisiana v. Becerra*, No. 21-30734, 2021 WL 5913302 (5th Cir. Dec. 15, 2021) (staying a universal injunction to an HHS vaccination requirement for Medicare and Medicaid facilities to the extent it applied to nonparties). For all of these reasons, Plaintiffs' motions should be denied.

## **BACKGROUND**

### **I. The COVID-19 Pandemic Has Had Devastating Effects.**

The novel coronavirus SARS-CoV-2 causes a severe acute respiratory disease known as COVID-19. 86 Fed. Reg. at 68,052. SARS-CoV-2 is primarily transmissible through exposure to respiratory droplets when one person is in close contact with another person who has COVID-19. As of December 2021, over 51 million COVID-19 cases and 800,000 COVID-19 deaths had been reported in the United States. *See* CDC, COVID Data Tracker, <https://perma.cc/4CNT-7SKN> (last visited Dec. 23, 2021) (cited at 86 Fed. Reg. at 68,052 n.6). COVID-19 has had a disproportionate effect on low-income and minority communities. 86 Fed. Reg. at 68,054–56.

Because the virus that causes COVID-19 is highly transmissible, it readily spreads among unvaccinated individuals in classroom settings, even when infection control practices are followed. *Id.* at 68,053. Unvaccinated educators are at a much higher risk of infection and, therefore, pose a higher risk of transmitting the virus to young unvaccinated children in their care. *Id.* Studies have also shown that a lack of consistent mask usage in schools is associated with a higher risk of transmission.<sup>1</sup>

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<sup>1</sup> *See id.* at 68,056 & nn.47–48 (citing Tracy Lam-Hine, Stephen A. McCurdy, Lisa Santora, et

Transmission of SARS-CoV-2 in child care settings often leads to infection and hospitalization in family members, including family members who are more susceptible to the effects of COVID-19 due to age or underlying condition. *Id.* at 68,055. When a child or staff member tests positive or is exposed to someone who has tested positive for SARS-CoV-2, classrooms and school programs often must be closed for days or weeks to allow time to receive test results and for quarantining. *Id.* Closures impose hardship on Head Start children and families by preventing in-person attendance in Head Start, thereby impairing early learning and development and diminishing the ability of parents to work. *Id.*

In June and July 2021, an especially contagious strain of SARS-CoV-2 known as the Delta variant drove dramatic increases in COVID-19 case and hospitalization rates throughout the United States. *Id.* at 68,052 & n.4 (citing CDC, Delta Variant: What We Know About the Science (Aug. 26, 2021), <https://perma.cc/4YRA-UWSP>). The Delta variant is associated with a higher risk of hospitalization in children: From June to mid-August 2021, weekly COVID-19-related hospitalizations among children and adolescents were nearly five times higher than in the preceding months. *Id.* at 68,054 & n.26 (citing Miranda J. Delahoy, Dawud Ujamaa, Michael Whitaker, et al. Hospitalizations Associated with COVID-19 Among Children and Adolescents—COVID-NET, 14 States, March 1, 2020–August 14, 2021, (Sept. 10, 2021), MMWR Morb. Mortal Wkly. Rep. 2021; 70:1255–60, <https://perma.cc/F535-GXNZ> (noting also that hospitalization among children ages four and below increased tenfold)). Vaccination and mask usage remain effective mitigation strategies against the Delta variant. *Id.*

When the Secretary issued the Rule, there were troubling indications of a resurgence of the virus in the forthcoming winter months. *Id.* at 68,058; CDC, COVID Data Tracker, <https://>

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al. Outbreak Associated with SARS-CoV-2 B.1.617.2 (Delta) Variant in an Elementary School—Marin County, California, May–June 2021, (Sept. 3, 2021), MMWR Morb. Mortal Wkly. Rep. 2021; 70:1214, <https://perma.cc/27TA-622J>; Megan Jehn, J. Mac McCullough, Ariella P. Dale, et al. Association Between K-12 School Mask Policies and School-Associated COVID-19 Outbreaks—Maricopa and Pima Counties, Arizona, July–August 2021, (Sept. 24, 2021), MMWR Morb. Mortal Wkly. Rep. 2021; 70:1372–73, <https://perma.cc/Z9YT-3P28>).

perma.cc/4CNT-7SKN (last visited Dec. 23, 2021). Respiratory viruses, like SARS-CoV-2, typically circulate more easily in cold weather, and the United States experienced a large spike in COVID-19 cases during the winter of 2020. 86 Fed. Reg. at 68,058. Indeed, since the Secretary issued the rule, the U.S. has seen a sharp increase in cases, *see* CDC, COVID Data Tracker, <https://perma.cc/4CNT-7SKN> (last visited Dec. 23, 2021), owing in part to the newly emergent Omicron variant, *see* CDC, Omicron Variant: What You Need to Know, <https://perma.cc/K9GN-KGG2> (Dec. 20, 2021).

## **II. Safe and Effective Vaccines and Masks Are Widely Available in the United States.**

Currently, three manufacturers offer vaccines approved or authorized for emergency use in the United States by the Food and Drug Administration (“FDA”). *See* 86 Fed. Reg. at 68,052. These vaccines are manufactured by Pfizer-BioNTech, Moderna, and Janssen (Johnson & Johnson), respectively. *Id.* On October 29, 2021, the FDA authorized the Pfizer-BioNTech vaccine for use in children ages five and up. *Id.* at 68,059. There is currently no vaccine available in the United States for children under the age of five. *Id.*

These vaccines are highly effective at preventing serious outcomes of COVID-19, including severe disease, hospitalization, and death. *Id.* at 68,054–55. The available evidence indicates that these vaccines offer strong protection against all known variants of the virus, including the Delta variant—particularly against hospitalization and death. *Id.* at 68,054. Recent studies indicate that the vaccines are 80% effective in preventing SARS-CoV-2 infection among frontline workers—more effective in practice than other protocols, such as regular testing. *Id.* at 68,059 & n.74 (citing Ashley Fowlkes, Manjusha Gaglani, Kimberly Groover, et al., Effectiveness of COVID-19 Vaccines in Preventing SARS-CoV-2 Infection Among Frontline Workers Before and During B.1.617.2 (Delta) Variant Predominance—Eight U.S. Locations, December 2020–August 2021, (Aug. 27, 2021), MMWR Morb. Mortal Wkly. Rep. 2021; 70:1167–69, <https://perma.cc/5YKH-QYR4>).

Like all vaccines, COVID-19 vaccines are not 100% effective at preventing infection, and some breakthrough cases are expected among people who are fully vaccinated. However, the risk of

developing COVID-19 remains much higher for unvaccinated than for vaccinated people, and therefore the presence of unvaccinated personnel is expected to lead to higher rates of transmission to other Head Start personnel and students. *Id.* at 68,055 & n.74. Vaccinated people with breakthrough COVID-19 cases are less likely to develop serious disease, be hospitalized, and die than those who are unvaccinated and get COVID-19. *Id.* at 68,059 (citing Fowlkes, et al., *supra*). Studies have also shown that vaccinated people with breakthrough infections may be less infectious than unvaccinated individuals with primary infections, resulting in fewer opportunities for transmission. *Id.* at 68,059.

Because children under age five cannot receive a COVID-19 vaccine at this time, masking remains an important mitigation strategy, along with vaccination among older individuals with whom young children come in contact. *Id.* at 68,055.

### **III. The Head Start Act Grants the Secretary the Authority to Issue Performance Standards Related to Health and Safety of Participants and Employees in Head Start.**

Head Start is a federal discretionary grant program that promotes school readiness in low-income children up to age five. 42 U.S.C. § 9831. Children under age three are eligible for the related Early Head Start program. *Id.* § 9840a. The Head Start program began as a summer program and demonstration grant in 1964, and in 1974 the Headstart–Follow Through Act made it a permanent program. Headstart, Economic Opportunity, & Community Partnership Act of 1974, Pub. L. No. 93-644, 88 Stat. 2291. The Head Start program is administered by the Office of Head Start (“OHS”), within the Administration for Children and Families (“ACF”) of the Department of Health and Human Services (“HHS”). Head Start is a direct federal-to-local grant that does not pass through the state.

The Headstart–Follow Through Act required the Secretary of Health, Education, and Welfare (predecessor to HHS) to issue regulations prescribing standards for Head Start grantees. Pub. L. No. 93-644, § 8(a), 88 Stat. 2291, 2300. Since 1975, these standards, known as the Head Start Performance Standards, have included comprehensive health screening for children. 45 C.F.R. § 1304.3-3(b)(4)–

(5), 1304.3-4(2) (1975). Over the years, additional health-related performance standards have been added. And in 1996, HHS added health screenings for staff and regular volunteers. 61 Fed. Reg. at 57,210, 57,223.

Because of the discretionary nature of Head Start grants, all participants necessarily agree to abide by the standards HHS sets when they voluntarily seek to join the program. *See* HHS, Grant Policy Statement, at I-1, I-3 to I-4 (Jan. 1, 2007), <https://perma.cc/PME5-9724>. No one is entitled to a Head Start grant or to attend a Head Start program. As a discretionary grant, the federal government maintains the authority to choose which entities receive grants. *See id.* Any entity that chooses to apply for and receives a Head Start grant agrees that it will meet the performance standards HHS imposes, even if those entities are school districts or educational institutions. *See id.*

Head Start is not a universal program, nor does it dominate early childhood care in the United States. Of the 24.6 million children ages five and under in the United States, *see* Forum on Child and Family Statistics, <https://perma.cc/8EU9-V2HA> (last visited Dec. 23, 2021), only 864,289 are currently enrolled in Head Start programs, 86 Fed. Reg. at 68,077. Many alternative pre-kindergarten programs are available to families that object to the Head Start Performance Standards. For example, many school districts provide, in the same schools, both Head Start pre-K services and non-Head Start pre-K services, the latter of which are not subject to the Head Start standards or the Rule. *See* Decl. of Jami Jo Thompson ¶ 2, Pls.' Ex. C, ECF No. 2-4; Decl. of Arthur M. Joffrion, Pls.' Ex. P, ECF No. 2-17. Alternative options are also available to entities that object to the Head Start Performance Standards, including health standards such as the Rule. For instance, before the COVID-19 pandemic began, one Maryland school system determined that it could no longer maintain the standards set for Head Start, so it relinquished its grant and provided services through its own non-Head Start pre-K program instead. *See* Donna St. George, *Head Start Expands in Md. County Where Scandal Flared Two Years Ago*, Washington Post (Sept. 12, 2018), <https://perma.cc/RB7C-YP5B>.

**IV. Recent Developments Have Revealed an Urgent Need for Further Action to Protect the Health of All Involved in Head Start.**

As noted above, the emergence of the Delta variant over the summer months led to a dramatic spike in cases, hospitalizations, and deaths caused by COVID-19, a resurgence that has been driven by the spread of infection among the unvaccinated population. The Secretary's initial policy approach after vaccines became available to the general population during the early months of 2021 was to encourage, rather than require, vaccination. 86 Fed. Reg. at 68,054. However, as the agency eventually determined, "uptake of vaccination among Head Start staff has not been as robust as hoped for and has been insufficient to create a safe environment for children and families." *Id.* The vaccination rate among Head Start personnel was estimated to be 77.1% on November 10, 2021. *Id.* at 68,070. In September 2021, the President announced his COVID-19 Action Plan, which set out a series of regulatory actions that federal agencies were planning to undertake in response to the pandemic. As relevant here, the announcement described HHS's plans to require vaccinations for teachers and personnel in Head Start programs. The White House, Path Out of the Pandemic, <https://perma.cc/M4GG-HB2Q> (last visited Nov. 24, 2021). On November 10, 2021, the CDC issued updated guidance to early childhood education and child care programs, which, among other things, recommended universal indoor masking for children ages two and older in these programs. 86 Fed. Reg. at 68,054 & n.28 (citing CDC, COVID-19 Guidance for Operating Early Care and Education/Child Care Programs, <https://perma.cc/6VRE-FRTR> (Nov. 10, 2021)).

**V. The Secretary Issued the Vaccination and Masking Rule to Protect the Health and Safety of All Involved in Head Start from the Transmission of SARS-CoV-2 in Head Start Facilities.**

On November 30, 2021, ACF published the interim final rule at issue here. The Rule adds to the Head Start Performance Standards a requirement that Head Start staff, volunteers, and contractors whose activities involve contact with or providing direct services to children and families in classrooms (collectively, "Head Start personnel") be fully vaccinated for COVID-19. 86 Fed. Reg. at 68,060. Under the Rule, all non-exempt personnel must receive the second dose of a two-dose COVID-19

vaccine or a single-dose COVID-19 vaccine by January 31, 2022. *Id.* at 68,052. Non-exempt individuals must provide documentation of their vaccination status. *Id.* at 68,061. Exemptions from the vaccination requirement will be granted by each Head Start program to individuals “who cannot be vaccinated because of a disability under the ADA, medical condition, or sincerely held religious beliefs, practice, or observance.” *Id.* Each Head Start program must establish a process for reviewing and reaching a determination regarding exemption requests. *Id.* Exempt individuals must be tested for COVID-19 on a weekly basis. *Id.* at 68,053.

The Rule also adds to the Head Start Performance Standards a universal masking requirement consistent with CDC recommendations. *Id.* at 68,060. All individuals ages two and over must wear a mask indoors in any setting where Head Start services are provided and inside any vehicle owned, leased, or arranged by the Head Start program. *Id.* Exceptions are permitted for individuals when they are eating or drinking, for children when they are napping, and for certain individuals who cannot wear a mask due to a disability.<sup>2</sup> *Id.* Unvaccinated individuals are also required to wear a mask outdoors in crowded settings or during activities that involve sustained close contact with other people. *Id.* The masking requirement became effective immediately upon publication of the Rule. *Id.* The Secretary also concluded that there was good cause to waive the notice-and-comment process in rulemaking. *Id.* at 68,058–59.

## **VI. The Present Controversy**

Plaintiffs now challenge the Rule, asserting claims purportedly arising under the United States Constitution, the Administrative Procedure Act (“APA”), and a variety of other statutes. Compl. ¶¶ 150–234, ECF No. 1. Plaintiffs filed their Complaint and moved for a preliminary injunction on December 21,

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<sup>2</sup> Contrary to Plaintiffs’ implication that the Rule will “force” some children participating in Head Start to “surrender their place,” PI Br. 5, a child cannot lose his or her place in Head Start because he or she refuses to wear a mask or a parent refuses to have a child wear a mask. Expelling a child from Head Start for behavior is prohibited. 45 C.F.R. § 1302.17(b). OHS has reminded grantees of this prohibition publicly in its FAQs for the Rule. *See* page FAQs on the IFC Vaccine and Masking Requirements at 6, <https://eclkc.ohs.acf.hhs.gov/sites/default/files/video/transcripts/002562-ifc-vaccine-masking-faq.pdf>.



2021. Compl.; Mot. Prelim. Inj. (“PI Br.”), ECF No. 2. Two days later, on December 23, 2021, Plaintiffs moved for a temporary restraining order. Mot. for TRO, ECF No. 6; Am. Mot. for TRO, ECF No. 7. The Court then ordered expedited briefing, requiring Defendants to respond to Plaintiffs’ motion for a temporary restraining order by December 29, 2021. Minute Entry (Dec. 23, 2021), ECF No. 9. And on December 27, 2021, the Court ordered Defendants to file an omnibus response and Plaintiffs to file an omnibus reply. ECF No. 12.<sup>3</sup>

### STANDARD OF REVIEW

“A preliminary injunction is an extraordinary and drastic remedy” that should “never be awarded as of right.” *Munaf v. Geren*, 553 U.S. 674, 689–90 (2008) (citation omitted). As is always the case, a plaintiff must first establish the court’s jurisdiction, including that the plaintiff has standing to bring its claims. *See Barber v. Bryant*, 860 F.3d 345, 352 (5th Cir. 2017). In addition, the plaintiff may obtain this “extraordinary remedy” only “upon a clear showing” that it is “entitled to such relief.” *Winter v. Nat. Res. Def. Council, Inc.*, 555 U.S. 7, 22 (2008). The plaintiff must show (1) “a substantial likelihood of success on the merits,” (2) “a substantial threat of irreparable injury,” (3) “that the threatened injury if the injunction is denied outweighs any harm that will result if the injunction is granted,” and (4) “that the grant of an injunction will not disserve the public interest.” *Jordan v. Fisher*, 823 F.3d 805, 809 (5th Cir. 2016) (quoting *Sepulvado v. Jindal*, 729 F.3d 413, 417 (5th Cir. 2013)). The plaintiff must “clearly carr[y] the burden of persuasion on all four requirements.” *Id.* (citation omitted); *see also, e.g., Lake Charles Diesel, Inc., v. Gen. Motors Corp.*, 328 F.3d 192, 203 (5th Cir. 2003). Although the court considers the same factors when evaluating a motion for a temporary restraining order, it scrutinizes them more closely. *See New Motor Vehicle Bd. of Cal. v. Orrin W. Fox Co.*, 434 U.S. 1345, 1347 n.2 (1977) (“A party seeking a restraining order must make a *persuasive* showing of irreparable harm and likelihood of prevailing on the merits” (emphasis added)); *cf. Dilworth v. Riner*, 343 F.2d 226,

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<sup>3</sup> On January 7, 2022, the U.S. Supreme Court will hear oral argument in cases involving vaccine requirements in two different contexts. *See* Order, *Biden v. Missouri*, No. 21A240 (Dec. 22, 2021); Order, *Becerra v. Louisiana*, No. 21A241 (Dec. 22, 2021); Order, *Nat’l Fed’n of Indep. Bus. v. Dep’t of Labor*, No. 21A244 (Dec. 22, 2021); Order, *Ohio v. Dep’t of Labor*, No. 21A247 (Dec. 22, 2021).



229 (5th Cir. 1965). The primary purpose of a temporary restraining order is to prevent immediate irreparable harm until the court considers issuing a preliminary injunction so where, as here, both have been simultaneously briefed, the preliminary injunction is the more appropriate remedy for the court to consider than a temporary restraining order. *See Wheat v. Craig*, No. 17-0424, 2017 WL 1106102 (W.D. La. Mar. 22, 2017).

## ARGUMENT

### I. Plaintiffs Lack Standing to Pursue Their Claims.

To establish standing, Plaintiffs must show that they have suffered an injury that is “concrete, particularized, and actual or imminent; fairly traceable to the challenged action; and redressable by a favorable ruling.” *Monsanto Co. v. Geertson Seed Farms*, 561 U.S. 139, 149 (2010). Where, as here, the case involves deciding “whether an action taken by one of the other two branches of the Federal Government was unconstitutional,” the “standing inquiry [is] especially rigorous.” *Raines v. Byrd*, 521 U.S. 811, 819–20 (1997).

Here Plaintiffs fail to meet “[t]he first and foremost of standing’s three elements,” injury in fact, *Spokeo, Inc. v. Robbins*, 578 U.S. 330, 338 (2016) (cleaned up), because they do not receive Head Start grants to operate classrooms. *Cf.* 86 Fed. Reg. 68,053 (describing the vaccination requirement as applying, with some exceptions to “all Head Start program staff, . . . , certain contractors, and volunteers *in classrooms or working directly with children*” (emphasis added)). To be eligible for classic Head Start grants, an entity must be a “*local* public or private nonprofit agency, including community-based and faith-based organization, or for-profit agency, within a community,” 42 U.S.C. § 9836(a)(1) (emphasis added), and Plaintiffs are thus not eligible for these grants. Plaintiffs have not alleged that they are recipients of traditional Early Head Start grants under 42 U.S.C. § 9840a.

Plaintiffs try to avoid this jurisdictional flaw by asserting that two Plaintiffs—Georgia and Utah—“directly participate as grantees.” Compl. ¶ 42. The facts, however, do not support this allegation. As Plaintiffs’ own exhibits verify, the recipient of the cited Utah grant is Southern Utah University, not the State of Utah. *See* Pls.’ Ex. O (Lisonbee Decl.) ¶¶ 4, 9. Plaintiffs’ reliance on the

Early Head Start–Childcare Partnership grant received by the Georgia Department of Early Care and Learning (“DECAL”) is likewise misplaced. *See* Pls.’ Ex. B (Jacob Decl.). That grant was made under the authority of multiple appropriations acts, not the Head Start Act. *See, e.g.,* Consolidated Appropriations Act, Pub. L. No. 116-260, 134 Stat. 1182, 1583 (2020). Unlike the grants provided to local entities to operate Head Start Programs under 42 U.S.C. § 9833, the grant received by Georgia is more administrative in nature. *See* Office of Head Start, *Early Head Start Child Care Partnership State Grantee Profile, Georgia* (Aug. 2016), [https://www.acf.hhs.gov/sites/default/files/documents/ecd/ga\\_ehsccp\\_grantee\\_profile\\_final.pdf](https://www.acf.hhs.gov/sites/default/files/documents/ecd/ga_ehsccp_grantee_profile_final.pdf); HHS, *Policy and Program Guidance for the Early Head Start–Partnerships (EHS–CCP) ACF-IM-HS-15-03*, <https://eclkc.ohs.acf.hhs.gov/policy/im/acf-im-hs-15-03-attachment>. Accordingly, DECAL does not operate a Head Start classroom or provide direct services to Head Start students. And while Plaintiffs’ declarations suggest that “DECAL staff frequently visit Head Start programs or meet[] with Head Start Families,” Pls.’ Ex. B ¶ 11, ECF No. 2-3, it is not clear if this involves actual contact with children. *Cf.* 86 Fed. Reg. 68,101 (updating 45 C.F.R. § 1302.93 to apply the vaccination requirement to “[a]ll staff, and those contractors whose activities involve contact with or providing direct services to children and families” with certain exceptions). Even if Georgia and Utah had standing, the other 22 states do not have standing. Plaintiffs’ attempt to establish “injury” by relying on the collaborative grants that states may receive under 42 U.S.C. § 9837b has no merit. Such grants assist states in facilitating collaboration among Head Start agencies and other entities providing early childhood education and development. *See* 42 U.S.C. § 9837b(2), (4). Plaintiffs assert that the new obligations imposed on Head Start agencies will make it more difficult for states to promote collaboration and coordination because many entities with which Head Start programs collaborate and coordinate do not impose vaccine and masking requirements. Compl. ¶¶ 144–46. This claim, however, is purely speculative. Collaboration and

coordination does not necessarily mean that non-Head Start personnel would be directly interacting with Head Start children in their classrooms.<sup>4</sup>

Plaintiffs’ attempt to invoke *parens patriae* (Compl. ¶ 57) also has no merit. As the Supreme Court recognized, “a state does not have standing as *parens patriae* to bring an action against the federal government to vindicate the rights of its citizens.” *Chiles v. Thornburgh*, 865 F.2d 1197, 1209 (11th Cir. 1989) (citing *Alfred L. Snapp & Son, Inc. v. Puerto Rico*, 458 U.S. 592, 610 n.16 (1982)). Although a state may have standing to vindicate its own injuries, see *Massachusetts v. EPA*, 549 U.S. 497, 519, 520 n.17 (2007) (injury to state’s interest as a coastal property owner), the states here are asserting an injury on behalf of a certain subset of their citizens: children in poverty. Whatever injuries these children and their families may claim, the states are not in a position to bring suit on their behalf. See *Brackeen v. Haaland*, 994 F.3d 249, 292 n.13 (5th Cir. 2021) (en banc) (“[A] State [does not] have standing as the parent of its citizens . . . against the Federal Government, the ultimate *parens patriae* of every American citizen.” (alterations in original) (quoting *South Carolina v. Katzenbach*, 383 U.S. 301, 324 (1966))), *cert. denied*, No. 21-380 (U.S. Sept. 8, 2021).

## **II. Plaintiffs Are Unlikely to Succeed on the Merits of Their Claims.**

### **A. The Rule Is Authorized by Statute.**

The vaccination and masking requirements fall within the Secretary’s “broad rule-making powers.” *Thorpe v. Hous. Auth. of City of Durham*, 393 U.S. 268, 277 n.28 (1969); see also *Nat’l Welfare Rts. Org. v. Mathews*, 533 F.2d 637, 640 (D.C. Cir. 1976) (referencing Congress’s “broad grant of power” to the Secretary).

#### **1. The Plain Statutory Text Authorizes the Rule.**

Like any other question of statutory interpretation, an analysis of an agency’s statutory authority “begins with the statutory text”—and, when the text is clear, it “ends there as well.” *Nat’l*

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<sup>4</sup> Because Plaintiffs do not have grants that are directly impacted by the Rule, the facts here are clearly distinguishable from the circumstances in *Louisiana v. Biden*, No. 21-3867 (W.D. La. Dec. 16, 2021), where the states had grants directly impacted by the challenged rule.

*Ass'n of Mfrs. v. Dep't of Def.*, 138 S. Ct. 617, 631 (2018) (citation omitted); see, e.g., *Little Sisters of the Poor Saints Peter & Paul Home v. Pennsylvania*, 140 S. Ct. 2367, 2380 (2020). Plaintiffs contend, based entirely on what they refer to as the “[m]ajor question[]” doctrine, that the statute’s failure to expressly mention vaccination and masking means that Congress did not grant the Secretary authority to protect Head Start participants’ and personnel’s health and safety in this manner. PI Br. 6. Even assuming that the major question doctrine were conceptually relevant, the Rule is not an exercise of “unheralded power to regulate ‘a significant portion of the American economy,’” *Utility Air Regul. Grp. v. EPA*, 573 U.S. 302, 324 (2014) (quoting *Food & Drug Admin. v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 159 (2000)). To the contrary, vaccine requirements have long existed as a commonplace feature of American life. See, e.g., *Klaassen v. Trs. of Ind. Univ.*, 7 F.4th 592, 593 (7th Cir. 2021) (Easterbrook, J.) (discussing *Jacobson v. Massachusetts*, 197 U.S. 11 (1905)), application for stay denied, No. 21A15 (Aug. 12, 2021). And as noted, the Head Start program is a discretionary federal grant program, not a universal preschool program; the Rule applies only to the 273,000 staff and 864,289 children who are part of the program, 86 Fed. Reg. at 68,077, as compared to, for example, the recent Occupational Safety and Health Administration (“OSHA”) vaccine rule that applies to over 80 million workers in America, *id.* at 68,069; see *BST Holdings, L.L.C. v. Occupational Safety & Health Admin.*, 17 F.4th 604, 617 (5th Cir. 2021), *stay dissolved*, *In re MCP No. 165*, ---F.4th---, 2021 WL 5989357, at \*19 (6th Cir. Dec. 17, 2021),<sup>5</sup> or the Centers for Medicare & Medicaid Services (“CMS”) vaccine rule at issue in the matter of *Louisiana v. Beccerra* that applied to “over 10.3 million health care workers,” No. 3:12-CV-03970, 2021 WL 5609846, at \*1 (W.D. La. Nov. 30, 2021). Additionally, many schools already require masks and require that their staff be vaccinated against COVID-19 for reasons paralleling those that led the Secretary to adopt the Rule.

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<sup>5</sup> Plaintiffs’ reliance on *BST Holdings* throughout their brief is misplaced. The now-dissolved stay in that case addressed the scope of agency authority under a different statute, enacted pursuant to Congress’s Commerce Clause power. Nothing in that case calls into question the Secretary’s ability to require recipients of federal Head Start grants to meet health and safety standards for the protection of school staff and children.

Moreover, the interpretive canon on which Plaintiffs rely “may only be used where words are of obscure or doubtful meaning.” *Iverson v. United States*, 973 F.3d 843, 853 (8th Cir. 2020) (citing *Russell Motor Car Co. v. United States*, 261 U.S. 514, 520 (1923)). Here, where the statutory text has “a character of its own” that plainly encompasses preventing Head Start children from being infected with a deadly disease and the intermittent closure of Head Start programs due to the transmission of disease, this canon is inapplicable. *Russell Motor Car*, 261 U.S. at 519. And, in any event, this canon does not apply “unless it is fair to suppose that Congress considered the unnamed possibility and meant to say no to it.” *Coastal Conservation Ass’n v. Dep’t of Com.*, 846 F.3d 99, 106 (5th Cir. 2017) (citation omitted). Plaintiffs can point to no statutory text that would indicate that Congress meant the statutory language here to mean anything other than its natural implication, which includes the protection of Head Start participants and personnel from contracting highly infectious diseases that would render young children unable to obtain the critical benefits of the Head Start program. The Secretary’s authority to adopt the Rule flows directly from the unambiguous text of the statute.

Congress charged the Secretary with adopting “standards relating to the condition . . . of [Head Start] facilities,” as well as to address other “administrative . . . standards” necessary for safely carrying out day-to-day operations of Head Start programs. 42 U.S.C. § 9836a(a)(1)(C), (D). Moreover, Congress vested the Secretary with broad authority to issue “such other standards as the Secretary finds to be appropriate” for Head Start agencies and programs. 42 U.S.C. § 9836a(a)(1)(E). Binding Supreme Court case law confirms the extent of the Secretary’s authority under these statutes. Addressing similar enabling language in other statutes, the Supreme Court has concluded that this language grants the agency “broad authority.” *Mourning v. Family Publ’ns Serv., Inc.*, 411 U.S. 356, 365 (1973) (quotation marks omitted). More specifically, “[w]here the empowering provision of a statute states simply that the agency may ‘make . . . such rules and regulations as may be necessary to carry out the provisions of this Act,’” the Court held that “the validity of a regulation promulgated thereunder will be sustained so long as it is ‘reasonably related to the purposes of the enabling

legislation.” *Id.* at 369 (quoting *Thorpe*, 393 U.S. at 280–81). The same is true of statutes that authorize regulations as the Secretary finds to be “appropriate.” *See, e.g., Arkansas v. Oklahoma*, 503 U.S. 91, 105 (1992); *GEO Grp., Inc. v. Newsom*, 15 F.4th 919, 930 (9th Cir. 2021) (“statutory language—‘appropriate’ and ‘necessary and proper’—is a hallmark of vast discretion” (footnote omitted)).

The Secretary’s authority to identify and order the correction of “deficienc[ies]” in Head Start programs reinforces his authority to issue the Rule. 42 U.S.C. § 9836a(e)(1). The Act defines a “deficiency” as “a systematic or substantial material failure of an agency in an area of performance that the Secretary determines involves—(i) a threat to the health, safety, or civil rights of children or staff; [or] (iii) a failure to comply with standards related to early childhood development and health services . . . .” *Id.* § 9832(2)(A). Because the Secretary can issue deficiencies on failures to follow standards that are a threat to health and safety, it follows that he can establish “standards related to early childhood development and health services” and “the health . . . of children or staff.”

The vaccination and masking Rule is comfortably within the Secretary’s authority because it is reasonably related to the purposes of the Head Start Act. By requiring vaccines and masking for certain Head Start personnel and participants under certain circumstances and subject to exemptions, the Secretary adopted an “administrative standard” “necessary” for the safe management of Head Start programs, 42 U.S.C. § 9836a(a)(1)(C), and also “relating to the condition . . . of facilities” to ensure they do not become places of viral contagion, *id.* § 9836a(a)(1)(D). At a bare minimum, the Secretary adopted a “standard[]” he found to be “appropriate” for the Head Start program. *Id.* § 9836a(a)(1)(E).

As noted above, Congress created the Head Start program as a means to provide a healthy and safe learning environment for low-income children across the country. This measure was “appropriate” to protect student health. The agency began by noting a CDC report that showed that over 51 million COVID-19 cases and 800,000 COVID-19 deaths had been reported in the United States. *See* CDC, COVID Data Tracker, <https://perma.cc/4CNT-7SKN> (last visited Dec. 23, 2021)

(cited at 86 Fed. Reg. at 68,052 n.6). It then explained that “vaccination is the most important measure for reducing risk for SARS-CoV-2 transmission and in avoiding severe illness, hospitalization, and death.” 86 Fed. Reg. at 68,052 (footnote omitted). HHS went on to reason that “[g]iven that children under age 5 years are too young to be vaccinated at this time, requiring masking and vaccination among everyone who is eligible are the best defenses against COVID-19.” *Id.* at 68,055. HHS further noted that in addition to protecting individuals from COVID-19, the requirements will “reduce closures of Head Start programs, which can cause hardship for families, and support the Administration’s priority of sustained in-person early care and education that is safe for children—with all of its known benefits to children and families.” *Id.* (footnote omitted). In short, the agency spelled out the connection between the Rule and the purposes of the Head Start Act.

## **2. The History of Past Head Start Regulations Confirms that the Rule is a Necessary and Appropriate Modification.**

Plaintiffs make much of the supposed limits of the phrase “modifying” in 42 U.S.C. § 9836a(a)(1), which directs that “[t]he Secretary shall modify, as necessary, program performance standards by regulation applicable to Head Start agencies and programs under this subchapter.” 42 U.S.C. § 9836a. Plaintiffs argue that the phrase cannot plausibly be read to allow the Secretary to establish regulations impacting the health of Head Start participants and employees. But even under the Plaintiffs’ own first definition of this term as “[t]o make somewhat different; to make small changes to (something) by way of improvement, suitability, or effectiveness,” PI Br. 8 (quoting *Modify*, Black’s Law Dictionary (10th ed. 2014)), the Secretary’s rule is authorized. Requiring masking of children over age two and staff vaccinations against a deadly and highly contagious disease are two moderate improvements to a program whose purpose addresses all facets of students’ readiness to succeed in an academic setting, including their health and safety (and that of their families). *See* 42 U.S.C. § 9831(2) (“It is the purpose of this subchapter to promote the school readiness of low-income children by enhancing their cognitive, social, and emotional development . . . through the provision to low-income children and their families of health, educational, nutritional, social, and other services



that are determined, based on family needs assessments, to be necessary.”).

Numerous provisions in the Head Start Act charge the Secretary with the responsibility to issue regulations, as he deems necessary, to protect the health and safety of program participants and personnel. The statutory provisions show that the health of children is a relevant consideration in the broader context of the statute. The Head Start Act directs that funding be used by Head Start agencies to provide “intensive training and technical assistance” for “[a]ctivities . . . to support . . . health services, and other services necessary to address the needs of children enrolled in Head Start programs.” *Id.* § 9843(d)(1)(G). Other provisions are similarly in accord. *See id.* § 9832(21)(G)(i) (defining the “professional development” of “Head Start teachers and staff” that the act is intended to promote to include “activities that . . . assist teachers with . . . the acquisition of the content knowledge and teaching strategies needed to provide effective instruction and other school readiness services regarding . . . physical health and development”); *id.* § 9843(a)(3)(B)(xii)(VI), (b)(2)(D) (instructing the Secretary “to the maximum extent practicable” to “assist Head Start agencies and programs to address the unique needs of programs located in rural communities, including . . . removing barriers to obtain health screenings for Head Start participants in rural communities” and also to “support training for personnel . . . to recognize common health . . . problems in children for appropriate referral”). *See also id.* § 9835(m)(2) (directing the Secretary to establish rules requiring Head Start agencies to allow families of homeless children to apply to, enroll in, and attend Head Start programs while required documents, such as . . . immunization and other medical records . . . are obtained within a reasonable time frame”); *id.* § 9836a(a)(2)(C)(ii) (requiring the Secretary to consider the effects of any revisions in Head Start standards on the “quality, scope, or types of health . . . services required to be provided under such standards as in effect on December 12, 2007”).

ACF in fact has a long history of rulemaking related to Head Start health standards, including measures similar to the vaccine and mask requirements at issue here, to which Plaintiffs have never objected. The first Head Start Program Performance Standards were issued in 1975, and they included



comprehensive health screening that “should be carried out for all of the Head Start children,” including tests for anemia and tuberculosis as well as urinalyses. 45 C.F.R. § 1304.3-3(b)(4)–(6) (1975). Head Start staff were also required to verify immunizations records, *id.* § 1304.3-3(b)(8) (1975), and participants were required to complete all recommended immunizations, including for diphtheria/pertussis/tetanus, polio, rubeola, rubella, and mumps. 45 C.F.R. § 1304.3-4(2) (1975). These Standards are entitled to “peculiar weight” given that they were promulgated just a year after Congress made Head Start a permanent program and thus represent “a contemporaneous construction of a statute by the men charged with the responsibility of setting its machinery in motion; of making the parts work efficiently and smoothly while they are yet untried and new.” *Norwegian Nitrogen Prod. Co. v. United States*, 288 U.S. 294, 315 (1933); *see also Kisor v. Wilkie*, 139 S. Ct. 2400, 2426 (2019) (Gorsuch, J., concurring in the judgment) (“The government’s early, longstanding, and consistent interpretation of a statute, regulation, or other legal instrument could count as powerful evidence of its original public meaning.” (emphasis omitted)).

Over the years, Head Start requirements have evolved in response to the most pressing health and medical threats of the times. For example, in the 1990s, guidance as an appendix to the performance standards included the appropriate treatment of children with HIV. 45 C.F.R. § 1308 App’x (2015). In 1996, HHS added health examinations for staff and tuberculosis screening for staff and regular volunteers to the Head Start Program Performance Standards. 61 Fed. Reg. at 57,210, 57,223. And in response to suggestions in comments that it no longer made sense to single out tuberculosis, HHS revised the staff health standard in 2016 to include more general language about staff health and communicable diseases. Head Start Performance Standards, 81 Fed. Reg. 61,294, 61,357, 61,433 (Sept. 6, 2016). Up through 2015, HHS even specifically mandated vaccinations for pets of families with children enrolled in home-based Head Start programs. 45 C.F.R. § 1306.35(b)(2)(ix) (2015). Read in the context of the history of HHS Head Start rulemaking, the Rule is plainly the agency’s way of “mak[ing] somewhat different” the existing regulatory structure “by way

of improvement, suitability, or effectiveness.” PI Br. 8. (quoting *Modify*, Black’s Law Dictionary (10th ed. 2014)).

As noted above, health and wellness standards apply to staff, who are required to have “an initial health examination and a periodic re-examination as recommended by their health care provider in accordance with state, tribal, or local requirements, that include screeners or tests for communicable diseases, as appropriate.” 45 C.F.R. § 1302.93(a).

In turn, Head Start Programs have a responsibility to “ensure staff do not, because of communicable diseases, pose a significant risk to the health or safety of others in the program.” 45 C.F.R. § 1302.93(a). Current standards also include staff training on prevention and control of infectious diseases and establishing administrative procedures regarding protection from contagious diseases. 45 C.F.R. § 1302.47(b)(4)(i)(A) & (b)(7)(iii). Commonsense measures like demonstrably safe vaccines and masks are logically included in Head Start Programs’ preexisting obligations to prevent the spread of communicable diseases.

Current and past standards have also included regulations similar to the vaccine and mask requirements to avoid the spread of contagious diseases. In the past, standards have included spacing cribs three feet apart to avoid the spread of contagious diseases, 45 C.F.R. § 1304.22(e)(7) (2015), and temporarily excluding children with acute or short-term contagious illnesses, *id.* § 1304.22(b). Current regulations also require Head Start Programs to “[o]btain determinations from health care and oral health care professionals as to whether or not the child is up-to-date on a schedule of age appropriate preventative and oral health care,” including following “immunizations recommendations issued by the Centers for Disease Control and Prevention,” *id.* § 1302.42(b)(1)(i), which currently include the COVID-19 vaccine for most Americans over age five, *see* CDC, COVID-19 ACIP Vaccine Recommendations (Nov. 5, 2021), <https://perma.cc/B2U6-GFYR> (hereinafter “CDC ACIP Recommendations”). If a child is not up-to-date on vaccines, Head Start programs are directed to “[a]ssist parents with making arrangements to bring the child up-to-date as quickly as possible; and, if

necessary, directly facilitate provision of health services to bring the child up-to-date with parent consent.” 45 C.F.R. § 1302.42(b)(1)(ii). In order to accomplish this, Head Start programs are even permitted to “use program funds for professional medical and oral health services when no other source of funding is available.” *Id.* § 1302.42(e)(2). In addition, all Head Start personnel are required to meet the child care standards of the states in which they operate. 42 U.S.C. § 9837(c)(1)(E)(iii); *see also id.* § 9832(2)(A)(vi) (defining a program deficiency in part as the “failure to meet any other Federal or State requirements that the agency has shown an unwillingness or inability to correct”); 45 C.F.R. § 1304.5(a)(2)(viii) (specifying that failure to abide by applicable state requirements is a ground for termination).

All of the aforementioned health regulations, including those regarding vaccinations and communicable disease precautions, have been considered “modifications” to the existing Head Start regulatory structure ever since 1975. Indeed, prior to this lawsuit, none of the Head Start Performance Standards had ever been challenged. Entities in the Plaintiff states, some of which received their first Head Start grant as early as 1974, have abided by all of the Head Start Program Performance Standards, including the health standards such as health screening for staff and vaccination rules for participants, for decades. Those entities have never suggested that those standards should be limited to exclude health, nor have the states. Many of these entities applied and entered into the Head Start program with the knowledge that those standards already existed, and they accepted them. Yet now, as Head Start regulations continue to evolve to meet the challenges of the greatest public health threat of the present day—the global COVID-19 pandemic—Plaintiffs oppose the same sorts of health measures with which entities in their states have always complied. Plaintiffs’ history of compliance without complaint further undermines Plaintiffs’ argument that the Secretary somehow lacks statutory authority for the similar measures required in the Rule.

### **3. Nothing in the Statute Forecloses the Secretary’s Reading of the Statute.**

Because, at a minimum, nothing in the statute forecloses the agency’s interpretation of the

statute as including the authority to require masks and vaccinations, that interpretation also warrants deference. *See generally Gonzales v. Oregon*, 546 U.S. 243, 255–56 (2006) (*Chevron* deference is warranted “when it appears that Congress delegated authority to the agency generally to make rules carrying the force of law and that the agency interpretation claiming deference was promulgated in the exercise of that authority” (citation omitted)); *see also Florida v. Dep’t of Health & Hum. Servs.*, No. 21-14098 (11th Cir. Dec. 1, 2021), Order at 15–16 (“The imposition of a vaccine mandate as a condition on the receipt of federal funds to ensure patient safety within those facilities is not expressly foreclosed by this statute. There appears little likelihood of success on the APA claim.”).

In discussing the Secretary’s authority, Plaintiffs note the Supreme Court’s holding that regulations of vast economic significance “must be authorized by a clear statement of unambiguous congressional intent.” PI Br. 6 (citing *Ala. Ass’n of Realtors v. Dep’t of Health & Hum. Servs.*, 141 S. Ct. 2485, 2489 (2021) (per curiam)). As explained above, however, Congress did speak clearly by authorizing the Secretary to impose, *inter alia*, “standards relating to the condition . . . of [Head Start] facilities,” as well as to address other “administrative . . . standards” necessary for safely carrying out day-to-day operations of Head Start programs. 42 U.S.C. § 9836a(a)(1)(C), (D). Moreover, Congress gave the Secretary the authority to adopt any “other standards as the Secretary finds to be appropriate.” 42 U.S.C. § 9836a(a)(1)(E). “Congress could have limited [the Secretary’s] discretion in any number of ways, but it chose not to do so.” *Little Sisters of the Poor*, 140 S. Ct. at 2380. And courts may not “impos[e] limits on an agency’s discretion that are not supported by the text.” *Id.* at 2381. Plaintiffs can point to no statutory text that would indicate that Congress intended the broad powers it granted the Secretary over “administrative . . . standards,” “standards relating to the condition . . . of facilities,” and “such other standards as the Secretary finds to be appropriate” to mean anything other than their natural implication, which includes the protection of Head Start students and employees at federally-funded Head Start facilities from a virus that has killed more than 800,000 Americans. 42 U.S.C. § 9836a(a)(1)(E).

For this reason, Plaintiffs' reliance on *Alabama Ass'n of Realtors v. Department of Health & Human Services*, 141 S. Ct. 2485 (2021), is misplaced. There, the Supreme Court held that an eviction moratorium imposed by the CDC exceeded the agency's authority to "prevent the [interstate] introduction, transmission, or spread of communicable diseases[.]" 42 U.S.C. § 264(a). Reading that language in context, the Court held that its scope was informed by the next sentence "illustrating the kinds of measures that could be necessary," such as "fumigation" or "pest extermination." 141 S. Ct. at 2488. Those measures "directly relate to preventing the interstate spread of disease," whereas the eviction moratorium "relate[d] to interstate infection" only "indirectly," through the "downstream connection between eviction" and possible spread of COVID-19 by evicted individuals who move "from one State to another." *Id.*

Here, the connection between the vaccine and masking requirements and student and employee health and safety is clear and direct: By requiring program personnel and participants to take the measures that most effectively reduce the risk that they contract and spread the virus that causes COVID-19, the Secretary sought to reduce the risk that students and workers would contract the virus. *Cf. Florida v. Dep't of Health & Hum. Servs.*, ---F.4th---, 21-14098, 2021 WL 5768796, at \*12 (11th Cir. Dec. 6, 2021); *see generally Merck & Co. v. U.S. Dep't of Health & Hum. Servs.*, 962 F.3d 531, 537–38 (D.C. Cir. 2020) (distinguishing an invalid rule with only "a hoped-for trickle-down effect on the regulated programs" from a valid rule with "an actual and discernible nexus between the rule and the conduct or management of Medicare and Medicaid programs"). Moreover, should Head Start personnel and students become infected with COVID-19, all students' ability to learn is hampered. The Secretary is simply exercising long-recognized and common sense power to adopt health and safety conditions for federally-funded programs for youth that are already subject to extensive conditions of participation.

And there is no reason to think that Congress—which granted the Secretary broad authority to protect Head Start students and personnel precisely because it could not foresee all future threats

to participant health and safety—would have regarded a vaccine or masking requirement as a matter requiring specific authorization. *See* 153 Cong. Rec. S14375-02, S14376, 2007 WL 3375993 (daily ed. Nov. 14, 2007) (statement of Sen. Kennedy) (Head Start “provides the starting point for a child’s day, with a healthy meal each morning and a promise to parents that while they are at work and balancing two jobs, their children will see a doctor and dentist, and receive immunizations.”). To the contrary, vaccine requirements have existed for centuries as a commonplace feature of American life, particularly in the education context. *See, e.g., Klaassen*, 7 F.4th at 593; *see also Jacobson*, 197 U.S. at 25–35 (identifying vaccine requirements in the United States and other Western countries in the early 1800s). Head Start personnel already have to receive certain vaccinations and health screenings. *See supra* at 19–20. Thus, “when it comes to vaccination mandates, there was no reason for Congress to be more specific than authorizing the Secretary to make regulations.” *Florida*, 2021 WL 5768796, at \*12 (in the context of the Secretary’s rulemaking regarding Medicare and Medicaid facilities). Basic hygiene practices like hand washing, disinfecting surfaces, and now wearing face masks to prevent the spread of viruses are similarly commonplace. In fact, Head Start regulations already require many of these practices. *See* 45 C.F.R. § 1302.47(b)(4)(i)(A) (staying home when sick); *id.* § 1302.47(b)(6)(i) (hand hygiene); *id.* § 1302.47(b)(2)(i) (cleaning, sanitizing, and disinfecting); *id.* § 1302.47(b)(4)(i)(A) (physical distancing). At a bare minimum, the Secretary reasonably understood his authority to encompass this responsibility, and that understanding is entitled to deference from this Court. *See Northport Health Servs. of Ark., LLC v. Dep’t of Health & Hum. Servs.*, 14 F.4th 856, 870 (8th Cir. 2021).

## **B. The Rule Is Not Contrary to Law.**

Plaintiffs next argue that the Rule violates four specific statutory provisions, but there is no substance to these arguments. *First*, the Rule complies with 42 U.S.C. § 9836a(a)(2)(B)(x), which requires the Secretary to “take into consideration . . . the unique challenges faced by individual programs, including those programs that are seasonal or short term and those programs that serve rural populations.” *See* PI Br. 9–10. Plaintiffs provide no explanation regarding the basis for this

claim, but in any event, HHS plainly complied with this provision, as the Rule’s preamble confirms. *See, e.g.*, 86 Fed. Reg. 68,054 (“The Secretary also considered the circumstances and challenges typically facing children and families served by Head Start agencies including the disproportionate effect of COVID-19 on low-income communities served by Head Start agencies and the potential for devastating consequences for children and families of program closures and service interruptions due to SARS-CoV-2 exposures.”); *id.* at 68,066 (“ACF also considered whether to tie the universal masking requirement and the testing requirement to SARS-CoV-2 transmission rate” in individual communities but found “[i]t would be burdensome for this program to issue separate guidance across its service area to account for changing transmission levels across those counties”).

*Second*, the Rule complies with 42 U.S.C. § 9836a(2)(A), which requires the Secretary to “consult with experts in the fields of child development, early childhood education, child health care, family services . . . , administration, and financial management, and with persons with experience in the operation of Head Start programs.” *See* PI Br. 10. The Rule explains that the Secretary consulted with “experts in child health, including pediatricians, a pediatric infectious disease specialist, and the recommendations of the CDC and FDA.” 86 Fed. Reg. at 68,054. Plaintiffs state that this “comes nowhere close to meeting § 9836a(2)(A)’s specific requirements” but never actually explain why that is except to assert that HHS “failed to disclose who specifically it actually consulted.” PI Br. 10. Notably absent from 42 U.S.C. § 9836a(a)(2) is any requirement that the Secretary identify by name of the specific experts with whom he consulted. And Plaintiffs do not point to any authority requiring such specificity. *Cf.* 5 U.S.C. § 553(c) (requiring only “a concise general statement of [a final’s rule] basis and purpose”).

*Third*, the Rule complies with 42 U.S.C. § 9836a(a)(2)(C)(ii), which requires the Secretary to “ensure that any such revisions in the standards will not result in the elimination of or any reduction in quality, scope, or types of health, educational, parental involvement, nutritional, social, or other services required to be provided under such standards as in effect on December 12, 2007.” *See* PI Br.

10. Plaintiffs’ entire argument on this point is that, in their opinion, the rule will “exclud[e] children and reduc[e] eligible staff and volunteers.” *Id.* Plaintiffs’ assertions are speculative; as evidenced by vaccine requirements in other contexts, most people choose to comply with such requirements rather than leave their jobs. *See* 86 Fed. Reg. at 68,055 & nn.52–54. In fact, one of the Secretary’s primary reasons for adopting the Rule was to ensure the continuity of Head Start services, including the “health, educational, parental involvement, nutritional, social, or other services” such facilities provide.

42 U.S.C. § 9836a(a)(2)(C)(ii). The Secretary explained that he

considered the circumstances and challenges typically facing children and families served by Head Start agencies including the disproportionate effect of COVID-19 on low-income communities served by Head Start agencies and the potential for devastating consequences for children and families of program closures and service interruptions due to SARS-CoV-2 exposures.

86 Fed. Reg. at 68,054. The Secretary noted that in the absence of reasonable measures like the Rule to prevent the spread of COVID-19, there would likely be intermittent closures of Head Start programs or even a switch to providing services virtually, *id.* at 68,055, which could reduce the quality, scope, or types of services offered to something below pre-2007 levels.<sup>6</sup> To the extent parents choose to exclude their own children from Head Start because they do not want them to wear face masks, that is no different from parents choosing to exclude their children because they do not want them to receive immunizations or to receive all medical treatments on their state’s Early and Pediatric Screening, Diagnosis, and Treatment schedule, all of which are already required for participation in Head Start and which none of the twenty-four plaintiff states have ever challenged. *See* 45 C.F.R. § 1302.42(b)(1)(i). The same goes for Head Start personnel, who are already required to undergo a number of health assessments and screenings and take precautions to avoid transmitting infectious diseases. *See supra* at 19–20.

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<sup>6</sup> The vaccine requirement does not eliminate or reduce services from pre-2007 levels when tuberculosis screening, crib spacing, and temporary exclusion were required for contagious disease control. *See supra* at 19–20. Rather, it updates the performance standards so they address the realities of the current environment, and therefore, support the continuation of the quality, scope, and types of services at the same or higher level as pre-2007.



*Fourth*, the Rule complies with 42 U.S.C. § 9836a(b)(3)(B), which requires that any rule promulgated under Section 641A “shall not be used to exclude children from Head Start programs.” *See* PI Br. 10. As already explained immediately above, requiring masking does not reasonably exclude children any more than requiring vaccines and other standard health treatments, which Head Start has required for decades. In fact, HHS promulgated the Rule in large part to make Head Start programs available to more students during the COVID-19 pandemic. *See supra* at 4 (explaining how COVID-19 results in program closures, depriving Head Start children across the country from accessing the invaluable resources it provides). HHS plainly followed all the statutory criteria laid out in these four statutory provisions. Plaintiffs’ real qualm amounts to a policy disagreement, but that is not a basis for invalidating a rule under the APA.

### **C. The Rule Is Not Arbitrary and Capricious.**

Plaintiffs’ arbitrary-and-capricious claims fare no better. Agency action must be upheld in the face of an arbitrary-and-capricious challenge so long as the agency “articulate[s] a satisfactory explanation for [the] action including a rational connection between the facts found and the choice made.” *Little Sisters of the Poor*, 140 S. Ct. at 2383 (citation omitted). A court’s review is “narrow” and the court “is not to substitute its judgment for that of the agency.” *Motor Vehicle Mfrs. Ass’n of the U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983); *see also Ky. Coal Ass’n v. Tenn. Valley Auth.*, 804 F.3d 799, 801 (6th Cir. 2015) (APA standard is not an “invitation for judicial second-guessing”). Under this “deferential” standard, a court “simply ensures that the agency has acted within a zone of reasonableness and, in particular, has reasonably considered the relevant issues and reasonably explained the decision.” *FCC v. Prometheus Radio Project*, 141 S. Ct. 1150, 1158 (2021). Critically, “mere policy disagreement is not a basis for a reviewing court to declare agency action unlawful.” *N.C. Fisheries Ass’n, v. Gutierrez*, 518 F. Supp. 2d 62, 95 (D.D.C. 2007). Indeed, “[w]hether [the Court] would have done what the agency did is immaterial,” so long as the agency engages in an appropriate decisionmaking process. *Mingo Logan Coal Co. v. EPA*, 829 F.3d 710, 718 (D.C. Cir. 2016).

Furthermore, the Court's review of Plaintiffs' APA claims should be confined to the record before the agency. "[T]he focal point for judicial review should be the administrative record already in existence [on the basis of which the administrator's determination was made], not some new record made initially in the reviewing court." *La. Env't Soc'y, Inc. v. Dole*, 707 F.2d 116, 119 (5th Cir.1983) (quoting *Camp v. Pitts*, 411 U.S. 138, 142 (1973)). "[W]hen a party seeks review of agency action under the APA . . . , the district judge sits as an appellate tribunal." *Rempfer v. Sharfstein*, 583 F.3d 860, 865 (D.C. Cir. 2009) (quoting *Am. Bioscience, Inc. v. Thompson*, 269 F.3d 1077, 1083 (D.C. Cir. 2001)). Thus, the Court's review "is based on the agency record and limited to determining whether the agency acted arbitrarily or capriciously." *Id.* To the extent Plaintiffs seek to introduce expert opinions going to the merits, for example, addressing the wisdom of vaccine and masking requirements, Pls.' Exs. S, T, ECF No. 2-20, 2-21, those opinions are not a proper subject of APA review because they were not before the Secretary and are irrelevant to his decision.

Here, the agency adopted a reasonable Rule after considering the relevant issues. The fifty-page Rule reasonably explains the agency's decision, setting forth the justifications, weighing costs and benefits, considering alternative approaches, and providing an economic impact analysis. *See generally* 86 Fed. Reg. at 68,052–68,101. Plaintiffs lodge a litany of claims that the Rule is arbitrary and capricious. PI Br. 13–19. None of these claims has merit. Adopting Plaintiffs' numbering:

*First*, Plaintiffs argue that the Rule overlooked that staff or students might leave the program due to the Rule, or overlooked the effects on specific groups, like children with special needs or underserved communities. PI Br. 13–15. But the agency considered these factors. The agency explicitly considered that the Rule might result in staff vacancies, and stated that "[t]o value the countervailing risk of staff vacancies, [ACF] adopt[s] an assumption that each Head Start staff that quits in response to the interim final rule will leave a vacancy that lasts an average of two weeks." 86 Fed. Reg. at 68,091. The Rule also finds that, "[f]or each COVID-19 case averted, parents and caretakers experienced 190 hours of time savings." *Id.* One of the primary goals of the Rule is to

reduce instances in which a positive case of COVID-19 in the classroom results in program closures and service interruptions. *See* 86 Fed. Reg. at 68,054. Thus, the agency considered that some personnel and students may voluntarily leave the Head Start program over the new requirements, but nevertheless determined that those costs would be outweighed by the benefits of reducing COVID-19 transmission. Additionally, the Rule provides exemptions from the vaccine requirement for personnel “who cannot be vaccinated because of a disability under the ADA, medical condition, or sincerely held religious beliefs, practice, or observance.” 86 Fed. Reg. at 68,061 (footnote omitted).

While Plaintiffs argue that the agency failed to consider children with special needs, the agency did consider them, and provided exceptions to the masking requirements for “persons who cannot wear a mask, or cannot safely wear a mask, because of a disability as defined by the Americans with Disabilities Act (ADA), consistent with CDC guidance on disability exemptions; and for children with special health care needs, for whom programs should work together with parents and follow the advice of the child’s health care provider for the best type of face covering.” 86 Fed. Reg. at 68,060. The Rule relies on November 10, 2021 guidance from the CDC, which recommended “universal indoor masking for ECE programs for everyone aged 2 years and older” and found that “ECE [early childhood education and child care] program staff can model consistent and correct use for children aged 2 years or older in their care.” 86 Fed. Reg. at 68,054. It is reasonable for ACF to rely on the recommendation of CDC, an agency with scientific expertise in protection from infectious diseases, over competing information from non-governmental agencies. *See Balt. Gas & Elec. Co. v. Nat. Res. Def. Council, Inc.*, 462 U.S. 87, 103 (1983) (recognizing that courts must be at their “most deferential” when reviewing an agency’s “scientific determination”); *N.C. Fisheries Ass’n*, 518 F. Supp. 2d at 95 (“[M]ere policy disagreement is not a basis for a reviewing court to declare agency action unlawful.”). Courts are not to “second-guess[]” an agency’s “weighing of risks and benefits” associated with a rulemaking. *Dep’t of Com. v. New York*, 139 S. Ct. 2551, 2571 (2019).

The Rule also explicitly considers its impact on underserved children and communities in particular, concluding that the Rule would “promote[] public and community health and health equity for children and staff in Head Start programs” “[g]iven the disproportionate burden of COVID-19 deaths and lower vaccination rates among racial and ethnic minority groups.” 86 Fed. Reg. at 68,055–56 (footnotes omitted); *see also id.* at 68,058 (“Program closures [from positive COVID-19 cases] impede Head Start families from participating in the workplace, impose financial hardship on low wage workers who may not have paid time off to care for children who are in quarantine, create instability for children and families who depend on the Head Start program, and delay a full economic recovery for the nation.”).

*Second*, contrary to Plaintiffs’ argument, PI Br. 15–16, HHS did consider alternatives to the Rule. Indeed, the Rule has an entire section outlining a number of options considered but rejected by the Secretary. 86 Fed. Reg. at 68,066. Plaintiffs specifically refer to natural immunity and the potential for vaccine efficacy to decrease over time, claiming that the Rule is arbitrary because it did not offer natural immunity as an alternative to vaccination or mask wearing, and because it insufficiently considered changes in vaccine efficacy over time. PI Br. 15–16. The agency considered scientific literature on the efficacy of vaccines, and concluded that “[t]he COVID-19 vaccines are the safest and most effective way to protect individuals and the people with whom they live and work from infection and from severe illness and hospitalization if they contract the virus.” 86 Fed. Reg. at 68,054–55. The Rule supports this finding with numerous scientific studies.<sup>7</sup> *Id.* at 68,055 & nn.31–36. “When examining this kind of scientific determination, as opposed to simple findings of fact, a reviewing court must generally be at its most deferential.” *Balt. Gas & Elec. Co.*, 462 U.S. at 103. ACF reasonably

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<sup>7</sup> Indeed, the agency considered scientific literature that acknowledged and took into account the possibility that vaccine efficacy decreases as time from vaccination increases, but still concluded that COVID-19 vaccines are highly protective. *See* Fowlkes, et al., *supra* (finding that the evidence “further affirm[ed] the highly protective benefit of full vaccination up to and through the most recent summer U.S. COVID-19 pandemic waves” despite some apparent decrease in vaccine effectiveness, and noting that “[vaccine effectiveness] might also be declining as time since vaccination increases”) (cited at 86 Fed. Reg. 68,055 n.33).

concluded that, based on the evidence, vaccinations are a superior mitigation strategy, regardless of a recipient's supposed "natural immunity."

The agency's decision was based on the most reliable scientific evidence available, especially given the contrast between the inexorable and, at times, surging pace of the pandemic and the necessarily measured pace of scientific research. It is common for an agency "not [to] have perfect empirical or statistical data"—particularly on complex issues like the interplay between protection provided by prior infection and vaccines, or the efficacy of vaccination over time—the APA does not require such evidence before an agency may act. *Prometheus Radio Project*, 141 S. Ct. at 1160; *see also San Luis & Delta-Mendota Water Auth. v. Locke*, 776 F.3d 971, 995 (9th Cir. 2014) ("[Even] if the only available data is 'weak, and thus not dispositive,' an agency's reliance on such data 'does not render the agency's determination arbitrary and capricious.'" (quoting *Greenpeace Action v. Franklin*, 14 F.3d 1324, 1336 (9th Cir. 1992))). Indeed many, if not most, statistical analyses have some limitations regarding sample size, etc., but that does not mean that they do not also provide valuable information upon which an agency may rely. Here, ACF "made a reasonable predictive judgment based on the evidence it had," *Prometheus Radio Project*, 141 S. Ct. at 1160, which is all the APA requires.

*Third*, the Rule's rationale—to mitigate the spread of COVID-19 in Head Start programs—is not pretextual. *Contra* PI Br. 16–17. Plaintiffs try to cast the Rule as a sinister attempt "aimed at increasing vaccination rates throughout American society, writ large." PI Br. 16. But there was no need for the agency to "pigeonhole the Mandate into the Head Start Act's statutory factors," PI Br. 16—the Act's statutory factors have long permitted the Secretary to include health related standards. *See supra* at Part II.A.1-2. Nor, given the copious evidence about the effectiveness of vaccines in reducing the spread of COVID-19, *e.g.*, 86 Fed. Reg. at 68,059, is it at all surprising that other federal agencies, like OSHA or CMS, may have concluded it was vital to their own missions to require vaccination of individuals that participate in their programs or that are regulated by them.<sup>8</sup> The

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<sup>8</sup> The present state of the COVID-19 pandemic has significantly deteriorated even since

thorough explication in the fifty-page Rule of the Secretary's justifications and reasons likewise rebuts any accusation that his reasons are pretextual. And, of course, to the extent that the Rule is part of a broader focus by the administration to protect the health and safety of Americans, there is nothing unusual or unlawful about this. "[A] court may not set aside an agency's policymaking decision solely because it might have been influenced by political considerations or prompted by an Administration's priorities." *Dep't of Com.*, 139 S. Ct. at 2573. Unlike in *Department of Commerce v. New York*, here there is not a "significant mismatch between the decision the Secretary made and the rationale he provided." *Id.* at 2575.

*Fourth*, Plaintiffs' allusion to "reliance interests," PI Br. 17, is unavailing. Plaintiffs refer to their interest "in public and private Head Start programs continuing to operate under existing rules," PI Br. 17, but the Rule analyzed its costs and benefits and concluded that the benefits outweighed the costs. Likewise, Plaintiffs refer to Head Start providers' interests "in staffing their facilities under the existing rules without facing this new Mandate that threatens their workforce," PI Br. 17, which appears to reduce to their same argument that the Rule will cause employees to leave or endanger Head Start services, and Head Start workers' interests "in selecting a job and building a career under the existing rules," PI Br. 17, which appears to reduce to Plaintiffs' same argument that the Rule will harm Head Start employees. None of these interests implicates reliance in the traditional sense, *i.e.*, Plaintiffs do not allege that they undertook actions to their detriment because of representations that the agency had made to them about the future. Indeed, it would be difficult for Plaintiffs to argue that they relied on the prior rules to their detriment, given that they do not directly received Head Start grants to operate classrooms, and that they elsewhere question why the agency "did not require children to wear masks in the Head Start program before now, including when case numbers were higher . . . ." PI Br. 18. Furthermore, the Plaintiffs were well aware that the Performance Standards

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November, when this Court found that "infection and hospitalization rates are dropping" as part of the basis for finding a CMS vaccine rule to be arbitrary and capricious. *See Louisiana*, 2021 WL 5609846, at \*14.

were subject to modification, as the Head Start Act explicitly instructs the Secretary to “modify” them “as necessary.” 42 U.S.C. § 9836a. And, as discussed, the agency has long imposed vaccine requirements. In any event, as has previously been discussed, the agency considered that the Rule might result in some Head Start employees choosing to leave their jobs, but determined that the benefits of the Rule outweighed that risk. That Plaintiffs would have reached a different conclusion had they been weighing the potential benefits does not mean that the Rule is arbitrary or capricious.

*Fifth*, Plaintiffs misapprehend the issue when they argue that the agency failed to consider conflicting state laws. PI Br. 17–18. The agency recognized that some states have differing requirements (and indeed, if all states had uniform requirements that matched the Rule, the Rule would be unnecessary). As the Rule noted, pursuant to the Supremacy Clause, the Rule preempts any conflicting state laws, relieving any issues of uncertainty regarding which requirements Head Start providers should implement. *See, e.g.*, 86 Fed. Reg. at 68,061 (“[T]his IFC preempts the applicability of any state or local law providing for exemptions to the extent such law provides broader exemptions than provided for by federal law and are inconsistent with this IFC.”); *id.* at 68,063 (“In these cases, consistent with the Supremacy Clause of the Constitution, the agency intends that this rule preempts State and local laws to the extent the State and local laws conflict with this rule.”). The agency did not take this step lightly, and as part of its preemption analysis noted that it had “considered other alternatives [to preempting state law] (for example, relying entirely on measures such as voluntary vaccination, source control alone, and physical distancing) and has concluded that the mandate established by this rule is the minimum regulatory action necessary to achieve the objectives of the statute.” *Id.*

*Sixth*, the Rule is not arbitrary and capricious for failure to “account for differences in” community measures, transmission levels, hospitalization levels, or levels of infection across communities.” PI Br. 18.<sup>9</sup> The agency considered these issues, including whether to tie requirements

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<sup>9</sup> Plaintiffs liken the supposed overbreadth of this rule to the OSHA vaccine rule that the Fifth

to community transmission rates. 86 Fed. Reg. at 68,066. However, given the number of Head Start grant recipients and the fact that many serve entire states or cross state lines, the agency concluded that such an approach “would be burdensome for” a grant recipients operating over a large area. *Id.* It is not arbitrary or capricious for the agency to recognize that “children benefit from routine and predictability” and to “prioritiz[e] clear and transparent policy that is easy for grantees to follow across their service areas.” *Id.* And an agency’s action should be upheld where it acts within the “zone of reasonableness.” *Prometheus Radio Project*, 141 S. Ct. at 1158; *see also Nat’l Shooting Sports Found., Inc. v. Jones*, 716 F.3d 200, 214 (D.C. Cir. 2013) (“An agency has wide discretion in making line-drawing decisions and the relevant question is whether the agency’s [determination is] within a zone of reasonableness, not whether [it is] precisely right.” (cleaned up)).

*Seventh*, Plaintiffs speculate that some harm may occur because Head Start students attend school with non-Head Start students—without citing anything to substantiate this theoretical harm—and that HHS overlooked this potential harm. PI Br. 18. ACF, of course, only has authority to implement standards for Head Start programs, not other programs, and it is not arbitrary or capricious for it to cabin itself to that limitation. To the extent that there are discrepancies among policies applying to students at the same school, they result from state and local school districts’ decisions not to implement mask requirements that align with the federal standards for Head Start. And, given that the agency correctly concluded that the masking requirement would bring public health benefits, not harms, 86 Fed. Reg. at 68,099–100, it would likewise bring *benefits* if, in fact, the Rule led programs “to mandate masking on students who themselves are not part of the Head Start program,” PI Br. 18.

*Eighth* and finally, the Rule *did* engage with the “fundamental questions” that Plaintiffs argue it omitted. PI Br. 18–19. As to why the Secretary did not implement a mask requirement “before now, including when case numbers were higher and everybody was unvaccinated,” PI Br. 18, the Rule

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Circuit found to be “staggeringly overbroad.” PI Br. 18 (quoting *BST Holdings*, 14 F.4th at 615) (internal quotation marks omitted). There is no comparison. That Rule applied to “2 out of 3 private-sector employees in America.” *BST Holdings*, 14 F.4th at 615.



notes, among other considerations, that “the advent of the Delta variant and the potential for new variants,” and the “return to fully in-person services” in January 2022, justified a more robust approach, particularly given that “uptake of vaccination among Head Start staff has not been as robust as hoped for and has been insufficient to create a safe environment for children and families.” 86 Fed. Reg. at 68,054. In addition, on November 10, 2021, the CDC “issued updated guidance to early childhood education and child care (ECE) programs,” which, among other things, recommended “universal indoor masking for ECE programs for everyone aged 2 years and older.” *Id.* The changed circumstances, including the emergence of the Delta variant and the updated CDC recommendations shortly before ACF issued the Rule, justified the change in course. This is not unusual. “[A]gencies are expected to reevaluate the wisdom of their policies in response to changing factual circumstances.” *COMPTON v. FEC*, 978 F.3d 1325, 1335 (D.C. Cir. 2020). There is no heightened standard when an agency changes its policy so long as the agency shows that “the new policy is permissible under the statute, that there are good reasons for it, and that the agency believes it to be better, which the conscious change of course adequately indicates.” *FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 515 (2009). And while Plaintiffs criticize the Rule for including a masking requirement where President Biden’s COVID-19 action plan did not, PI Br. 18–19, the agency did consider an alternative that did not include a masking requirement, but concluded, in weighing the available evidence, that adding the masking requirement “will result in additional, unquantified reductions in mortality and morbidity risks to Head Start children and families, and to the general public.” 86 Fed. Reg. at 68,100. That Plaintiffs would have reached a different conclusion does not mean that the agency acted arbitrarily or capriciously.

**D. The Secretary Had Good Cause to Issue the Interim Rule Without Advance Notice and Comment.**

Notice-and-comment rulemaking is not required “when the agency for good cause finds (and incorporates the finding and a brief statement of reasons therefor in the rules issued) that notice and public procedure thereon are impracticable, unnecessary, or contrary to the public interest.” 5 U.S.C.

§ 553(b)(B). While this exception is often narrowly construed, an agency “should have more latitude in determining when to invoke ‘good cause’ when notice and comment requirements are self-imposed.” *Alcaraz v. Block*, 746 F.2d 593, 612 (9th Cir. 1984). Such is the case here. The text of the APA exempts rulemakings “relating to . . . grants” from its notice and comment requirements, 5 U.S.C. § 553(a)(2), and Head Start is a federal grant program, 42 U.S.C. §§ 9831 *et seq.* HHS has previously issued internal guidance saying that it “will use notice of proposed rule making procedures in certain cases where not required by law.” Public Participation in Rule Making, 36 Fed. Reg. 2,531, 2,532 (Feb. 5, 1971). But because the text of the APA “clearly indicates congressional intent that notice and comment shall not be required, with the agency thus acting in an extra-statutory fashion by adopting the requirements as its policy,” the “congressional policy for interpreting good cause extremely narrowly does not operate.” *Alcaraz*, 746 F.2d at 612.

The Secretary properly waived notice-and-comment procedures under the good cause exception here. *See* 86 Fed. Reg. at 68,058–59. The exception excuses notice and comment where delay could result in serious harm. *See Jifry v. FAA*, 370 F.3d 1174, 1179 (D.C. Cir. 2004). The Secretary found that any delay in issuing the Rule would “endanger the health and safety of staff, children and families, and be contrary to the public interest,” 86 Fed. Reg. at 68,059, given the Rule’s “life-saving importance,” *Council of S. Mountains, Inc. v. Donovan*, 653 F.2d 573, 581 (D.C. Cir. 1981). The emergence of the highly transmissible Delta variant, along with additional data showing the effectiveness of vaccines, amply justifies taking urgent measures. *See* 86 Fed. Reg. at 68,058. The Delta variant “has resulted in greater rates of cases and hospitalizations among children,” and in recent months, these rates have remained “elevated” compared to other points in the pandemic. *Id.* at 68,053, 68,055. Head Start involves young children under the age of five who cannot be vaccinated. *See id.* at 68,055. The 27% of Head Start personnel who are estimated to be unvaccinated “could result in roughly 250,000 children who are in the care of an unvaccinated adult.” *Id.* at 68,056. Given the Delta variant’s “higher impact on children,” *id.* at 68,055, it is even more pressing that this potential for

exposure is reduced immediately. *See Sorenson Comm'ns Inc. v. FCC*, 755 F.3d 702, 706 (D.C. Cir. 2014) (although good cause is rarely invoked, “we have approved an agency’s decision to bypass notice and comment where delay would imminently threaten life”). The Secretary acted because of these serious threats to health and safety—far more than the “administrative inconvenience” of Plaintiffs’ characterization. PI Br. 11.

Additionally, referencing the COVID-19 surge in the winter of 2020, the Secretary highlighted the potential for infection rates to increase in the coming months due to cold weather, 86 Fed. Reg. at 68,058. The Rule also noted that “there is potential for the rapid and unexpected development and spread of additional new and more transmissible variants,” *id.* at 68,053. Given these recent developments in a rapidly-changing pandemic landscape, the Secretary was more than justified in taking immediate action on additional COVID-19 precautions—particularly for those regularly interacting with young children who cannot be vaccinated. *See Roman Cath. Diocese of Brooklyn v. Cuomo*, 141 S. Ct. 63, 67 (2020) (“Stemming the spread of COVID-19 is unquestionably a compelling interest.”).

Plaintiffs argue that the Secretary should have issued the Rule earlier, PI Br. 12, but the Secretary “can and must be able to respond to dangers as they evolve.” *In re MCP No. 165*, 2021 WL 5989357, at \*9. As noted, *see supra* Part I.B.8, the Secretary initially chose a policy of “allow[ing] Head Start programs to decide whether or not to require staff vaccination.” 86 Fed. Reg. at 68,054. Because of the Delta variant, an expected return to fully in-person services in January 2022, as well as a vaccination uptake among Head Start personnel that “has not been as robust as hoped for,” *id.*, the Secretary’s issuance of the Rule when he did does not undermine the application of the good cause exception. And preparing the fifty-page rule, with its analysis of over 144 cited sources, took time. *Compare Asbestos Info. Ass’n/N. Am. v. Occupational Safety & Health Admin.*, 727 F.2d 415, 423 (5th Cir. 1984) (recognizing that good cause may be met even when the agency acts years after learning of a serious health risk, so long as the agency “offer[s] some explanation of its timing in promulgating” the

rule, and it “acted in response to new awareness of the danger”) *with* 86 Fed. Reg. at 68,052–68,101. Taking the time to craft a “reasoned policy determination” does not “undermine the state of emergency that this unprecedented pandemic currently presents,” *see In re MCP No. 165*, 2021 WL 5989357, at \*9, especially given the number of issues the Plaintiffs claim the Secretary should have taken more time to consider, *see supra* Part II.C.

Because the Secretary had good cause to dispense with notice and comment rulemaking, Plaintiffs’ argument in a footnote about the Congressional Review Act, PI Br. 13 n.1, is also unavailing. 5 U.S.C. § 808 simply grafts the APA’s good cause standard onto the Congressional Review Act. Moreover, 5 U.S.C. § 805 “denies courts the power to void rules on the basis of agency noncompliance with the [CRA].” *Montanans for Multiple Use v. Barbonletos*, 568 F.3d 225, 229 (D.C. Cir. 2009).

#### **E. The Rule Complies with the Treasury and General Government Appropriations Act of 1999.**

Plaintiffs’ contention that the agency violated the Treasury and General Government Appropriations Act here by not conducting a family impact assessment, PI Br. 19, is a red herring. As an initial matter, that statute is not judicially enforceable. *See* Public Law No. 105-277, 5 U.S.C. § 601 note (f) (“This section is not intended to create any right or benefit, substantive or procedural, enforceable at law by a party against the United States, its agencies, its officers, or any person.”). And in any event, the agency explained that it had followed the requirements of that statute. Section 654 of that act requires agencies to first determine whether a policy or regulation “may affect family well-being” and then, only if the policy or regulation may do so, to “assess such actions with respect to” seven different criteria. The agency explained that it followed the statutory requirement, stating, “ACF believes it is not necessary to prepare a family policymaking assessment . . . because the action it takes in this interim final rule will not have any impact on the autonomy or integrity of the family as an institution.” 86 Fed. Reg. at 68,062. The agency also “invite[d] public comment on whether the actions set forth in this interim final rule would have a negative effect on family well-being,” *id.*,

thereby leaving the door open to a future family impact assessment if and when it might become necessary.

Plaintiffs fault ACF for failing to conduct this assessment, but tellingly, they do not argue how the Rule “may affect family well-being,” 5 U.S.C. § 601 note (f), or assert that it was arbitrary or capricious for the agency to make the determination that the Rules does *not* affect family well-being. Rather, they include a single conclusory sentence that “[t]he mandate . . . intrudes into fundamental decisions about whether a child must wear a mask or not at school, imposes obligations on parents picking children up from school, and goes straight to the heart of the allocation of power between State and family.” PI Br. 19. Plaintiffs do not provide any support whatsoever for this statement, and the “extraordinary remedy” that they ask for—a temporary restraining order or preliminary injunction—cannot be predicated on conclusory statements and speculation but rather requires a “clear showing.” *Winter*, 555 U.S. at 22. Without arguing that ACF was wrong to determine that the Rule would not impact family well-being, Plaintiffs cannot argue that the assessment was required.

It makes sense that Plaintiffs do not argue, beyond their single unadorned sentence, that the Rule may affect family well-being given that the Rule simply requires two commonsense measures that slow the spread of a highly contagious virus while children are with their peers and personnel at Head Start facilities. When children are with their families at home or anywhere else, they are not covered by the Rule, so they are free to wear masks or not, as they and their families so choose. The seven factors included in the family impact assessment plainly do not apply to the requirements of the Rule. For example, there is no reason to believe Congress intended ACF to assess whether vaccine and mask requirements “strengthen[] or erode[] the stability or safety of the family and, particularly, the marital commitment” or “increase[] or decrease[] disposable income or poverty of families and children.” 5 U.S.C. § 601 note. Because Congress plainly did not intend that agencies apply these factors to a rule like this one, and Plaintiffs do not so much as argue how any of these specific factors would apply to this Rule, Plaintiffs are not likely to succeed on the merits of this claim.

**F. The Rule Complies with the Nondelegation Doctrine, Spending Clause, Tenth Amendment, and Anti-Commandeering Doctrine.**

Plaintiffs' remaining objections, PI Br. 19–22, also fail.

Contrary to Plaintiffs' non-delegation argument, PI Br. 19–20, “[d]elegations are constitutional so long as Congress lays down by legislative act an intelligible principle to which the person or body authorized to exercise the authority is directed to conform.” *Big Time Vapes, Inc. v. FDA*, 963 F.3d 436, 441 (5th Cir. 2020) (cleaned up), *cert. denied*, 141 S. Ct. 2746 (2021). Here, the Secretary's statutory authority to protect the health and safety of Head Start students and personnel easily meets this minimal standard. *Cf. Whitman v. Am. Trucking Ass'ns*, 531 U.S. 457, 473 (2001) (upholding “public health” standard). The Head Start Act delegates to the Secretary authority merely to set standards for the performance of the Head Start program, not to regulate broad swaths of the economy. Any performance standards under this statute, in addition to being “appropriate,” must of course further the purpose of the Head Start program, cabining the scope of the delegation.

Plaintiffs' Tenth Amendment argument, PI Br. 20–21, likewise fails because as long as federal action rests on a constitutionally delegated power, “there can be no violation of the Tenth Amendment,” *United States v. Mikbel*, 889 F.3d 1003, 1024 (9th Cir. 2018) (citation omitted), *cert. denied*, 140 S. Ct. 157 (2019); *accord United States v. Hatch*, 722 F.3d 1193, 1202 (10th Cir. 2013). As mentioned, 42 U.S.C. § 9836a(a)(1), under which the Rule was promulgated, was enacted pursuant to the Spending Clause, an evident exercise of Congress's legislative power under the Constitution. *See Valley Forge Christian Coll. v. Ams. United for Separation of Church & State, Inc.*, 454 U.S. 464, 480 (1982).

“Congress has authority under the Spending Clause to appropriate federal moneys to promote the general welfare, . . . [and] to see to it that taxpayer dollars appropriated under that power are in fact spent for the general welfare.” *Sabri v. United States*, 541 U.S. 600, 605 (2004). This power applies even when Congress legislates “in an area historically of state concern.” *Id.* at 608 n.\*. Plaintiffs' arguments that health and education are within the state's police powers, PI Br. 20, are thus of no moment. The Secretary did not intrude on state police powers when he issued the Rule, then, any

more than he did when he issued the long-standing rules conditioning federal funds on requiring that Head Start personnel do not “pose a significant risk” “of communicable disease.” 45 C.F.R. § 1302.93(a).

Nor would it matter if the Rule conflicted with the state’s own health and safety measures. Indeed, it is axiomatic that the federal government does not “invade[] areas reserved to the States by the Tenth Amendment simply because it exercises *its* authority” under the Constitution, even “in a manner that *displaces* the States’ exercise of their police powers.” *Hodel v. Va. Surface Mining & Reclamation Ass’n*, 452 U.S. 264, 291 (1981) (emphasis added); *accord Okla. ex rel. Okla. Dep’t of Pub. Safety v. United States*, 161 F.3d 1266, 1272 (10th Cir. 1998). Thus, “‘the Federal Government, when acting within a delegated power, may override countervailing state interests,’ whether those interests are labeled traditional, fundamental, or otherwise.” *Brackeen*, 994 F.3d at 310 (citation omitted); *see also In re MCP No. 165*, 2021 WL 5989357, at \*17 (“[T]hat states may regulate COVID-19 safety measures does not operate to preclude the federal government from doing so[.]”).

Nor does the Rule “commandeer” states into enforcing it. The Supreme Court has found improper commandeering when, for example, the federal government forced state legislatures to enact state regulations according to Congress’s instructions, *New York v. United States*, 505 U.S. 144, 161 (1992), or when the federal government “conscript[ed]” local law enforcement officials by requiring them to perform background checks in connection with firearms sales, *Printz v. United States*, 521 U.S. 898, 935 (1997).

The Rule does none of these things. For starters, as previously discussed, *see supra* Part I, the Plaintiffs, as states, are not even eligible for Head Start program grants under 42 U.S.C. § 9836 because they are not local entities, and they do not allege that they receive Early Head Start grants under 42 U.S.C. § 9840a. To the extent that states might interact with Head Start programs in various ways (for example, the partnership grant received by Georgia DECAL or collaborative grants to other states), this interaction does not lead to a commandeering problem. A state acts entirely voluntarily in

applying for such collaboration grants. In addition, the Rule merely amends the existing Performance Standards as authorized by 42 U.S.C. § 9836a(a)(1), which was enacted under the Spending Clause. Thus the Rule does not “requir[e] State entities to enforce” it, PI Br. 21, except inasmuch as state entities that have chosen to seek out collaboration grants are now collaborating with Head Start programs (not themselves operated by the states) that are required to uphold the preexisting Head Start Performance Standards *and* the Rule rather than just the preexisting Head Start Performance Standards. And the Plaintiff-states have apparently had no issues in the past collaborating with Head Start programs that were complying with Head Start Performance Standards. Finally, where, as here, “Congress places conditions on a State’s receipt of federal funds—whether directly, or by delegation of clarifying authority to an executive agency—there is no commandeering of reserved State power so long as the State has ‘a legitimate choice whether to accept the federal conditions in exchange for federal funds,’” *New York v. Dep’t of Just.*, 951 F.3d 84, 115 (2d Cir. 2020) (quoting *Nat’l Fed’n of Indep. Business v. Sebelius*, 567 U.S. 519, 578 (2012)); *see also Printz*, 521 U.S. at 916; *id.* at 936 (O’Connor, J., concurring) (“Congress is also free to amend the interim program to provide for its continuance on a contractual basis with the States if it wishes, as it does with a number of other federal programs.”), and there would thus be no commandeering issue even in the counterfactual world where the Rule *was* placing conditions on Plaintiffs’ use of federal funds.

Nor does the Rule violate the Spending Clause. *Contra* PI Br. 22. Under that clause, Congress may impose conditions on federal grants to States so long as it “do[es] so unambiguously” so “States [can] exercise their choice knowingly.” *Pennhurst State Sch. & Hosp. v. Halderman*, 451 U.S. 1, 17 (1981); *see also South Dakota v. Dole*, 483 U.S. 203, 206–07 (1987). Here, again, the Plaintiffs are not eligible for Head Start program grants because they are states, not local entities. To the extent that states have sought out other grants relating to Head Start, like collaboration grants or Georgia DECAL’s partnership grant, they have “knowingly” made the choice to take on those grants. Even if Plaintiffs were operators of Head Start programs subject to the Rule, the Rule unambiguously puts recipients



on notice that they are obligated to comply with the mask and vaccine requirements when they receive Head Start funding by clearly laying out the Rule’s three requirements: (1) universal masking for those two years or older; (2) vaccination for all Head Start personnel; and (3) weekly testing for those exempted from vaccination. A grant recipient thus will be capable of making “an informed,” voluntary decision whether to accept the attendant obligations of contracting with the Federal Government, avoiding any Spending Clause issue. *See Pennhurst*, 451 U.S. at 25; *see also Mayweathers v. Newland*, 314 F.3d 1062, 1067 (9th Cir. 2002) (“[T]he Supreme Court has held that conditions may be ‘largely indeterminate,’” and yet constitutionally permissible, as long as the States have clear notice that accepting funds “obligate[s them] to comply with [the conditions].” (quoting *Pennhurst*, 451 U.S. at 24–25)). Plaintiffs appear to think that the Head Start Act—not the Rule—is overly ambiguous. PI Br. 22. Were that the case, of course, that would be a reason to challenge the Head Start Act itself, not the Rule. But in any event, the Head Start Act unambiguously gives notice of the existence of conditions, *e.g.* 42 U.S.C. § 9836a, which is all that is required. And, contrary to Plaintiffs’ argument, PI Br. 22, there is a clear nexus between the Head Start Act’s instructions to the Secretary and the Rule here, *see supra* Part II.A.

Given that there is no constitutional problem with the Rule, there is no need for the Court to “avoid[],” PI Br. 22, the correct interpretation of the statute advanced by Defendants.

### **III. Plaintiffs Will Not Suffer Irreparable Harm Absent an Injunction.**

Plaintiffs also cannot demonstrate irreparable harm. When plaintiffs “fail[] to prove that, absent the injunction, irreparable injury will result,” the preliminary injunction “should be denied.” *Enter. Int’l, Inc. v. Corporacion Estatal Petrolera Ecuatoriana*, 762 F.2d 464, 472 (5th Cir. 1985). It is their burden to show that the harm of which they complain is likely and not merely possible. *Winter*, 555 U.S. at 20. “Speculative injury is not sufficient” “to make a clear showing of irreparable harm.” *Holland Am. Ins. Co. v. Succession of Roy*, 777 F.2d 992, 997 (5th Cir. 1985). Plaintiffs have not met their burden here.

Plaintiffs’ primary argument—that they will be irreparably harmed because the Rule “will cause them to lose direct federal funding,” PI Br. 23, fails because as previously discussed, *see supra* Part I, the Plaintiffs do not receive Head Start Program grants under 42 U.S.C. § 9836a because they are *states* rather than eligible local entities, nor do they allege that they receive Early Head Start grants under 42 U.S.C. § 9340a. Perhaps recognizing this, Plaintiffs also raise a more speculative theory that the Rule will cause “public schools to lose federal funding, cause public entities involved with Head Start—many of which will turn to States for additional funding—to spend their own money enforcing compliance and providing tests, and cause the States to spend more in public benefits.” PI Br. 23. But this chain of events—entities that are not plaintiffs incurring costs that they will somehow recoup from Plaintiffs, or Plaintiffs choosing to fund greater public benefits in the future—is highly uncertain and does not suffice to show irreparable harm. Even were that not the case, this supposed injury would fail as a matter of black-letter law. “[E]conomic loss such as the loss of funding is not irreparable.” *Florida v. Dep’t of Health & Human Servs.*, --- F. Supp. 3d ---, 2021 WL 5416122, at \*3 (N.D. Fla. Nov. 20, 2021), *appeal filed*, No. 21-14098 (11th Cir. Nov. 24, 2021); *see also Deerfield Med. Ctr. v. City of Deerfield Beach*, 661 F.2d 328, 338 (5th Cir. 1981). Notably, Plaintiffs do not identify any cases to the contrary.

Nor, as explained above, do Plaintiffs have standing as *parens patriae* to carve out their citizens from the operation of the Rule. *Contra* PI Br. 23–24. As the Supreme Court has made clear, a “[s]tate does not have standing as *parens patriae* to bring an action against the Federal Government,” except when the state can articulate “quasi-sovereign interests” apart from the interests of its citizens. *Snapp*, 458 U.S. at 610 n.16; *cf. Texas v. Biden*, ---F. Supp. 3d---, 2021 WL 3603341, at \*12 (N.D. Tex. Aug. 13, 2021) (Kacsmaryk, J.) (contrasting a permissible suit in which a State asserts its own rights under federal law with one in which a State is impermissibly “attempting to protect its citizens from the operation of [the federal law]”); *Florida v. Dep’t of Health & Hum. Servs.*, No. 21-cv-2722 (N.D. Fla. Dec. 1, 2021), Order at 7, ECF No. 18 (declining to find a *parens patriae* interest in a state law that

operates to “shield employees who choose to work in a federally funded healthcare facility from the rules that govern administration of the federal program”). The two alleged injuries to their citizens that Plaintiffs purport to rely on are “a reduction in the availability of Head Start services” and a burden on “the liberty interests of the preschool staff,” PI Br. 24, but neither of these is a quasi-sovereign interest such as the health of state residents or the state’s ability to create their own legal code, *Snapp*, 458 U.S. at 603–08, and Plaintiffs are thus nothing more than nominal parties attempting to assert interests that belong to their citizens.<sup>10</sup>

Plaintiffs’ argument that the Rule harms the state’s “sovereign interests” by preempting state law, PI Br. 24, likewise misses the mark. “[I]t is black-letter law that the federal government does not ‘invade[ ]’ areas of state sovereignty ‘simply because it exercises its authority’ in a way that preempts conflicting state laws.” *Florida*, 2021 WL 5768796, at \*15 (quoting *Hodel*, 452 U.S. at 291). As the Eleventh Circuit noted, to “conclude otherwise would mean that a state would suffer irreparable injury from all . . . federal laws with preemptive effect.” *Id.* Indeed, courts have recognized a cognizable Article III harm when a state’s *own* enforcement efforts have been hampered, not when a federal enactment merely raises the abstract question of whether state law is preempted. *See Va. ex rel. Cuccinelli v. Sebelius*, 656 F.3d 253, 271 (4th Cir. 2011) (“To permit a state to litigate whenever it enacts a statute declaring its opposition to federal law . . . would convert the federal judiciary into a ‘forum’ for the vindication of a state’s ‘generalized grievances about the conduct of government.’” (quoting *Flast v. Cohen*, 392 U.S. 83, 106 (1968))).

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<sup>10</sup> Even if the Plaintiff-states could represent the interests of their citizens against the Federal Government (and they cannot), Plaintiffs’ allegations of harm to their citizens—which Plaintiffs barely bother to explain—are entirely speculative. *Compare* Pls.’ Ex. C–G, I, J, K, O–Q (speculating about the possible effects of the Rule on various Head Start programs), *and* PI Br. 24 (citing Pls.’ Ex. L, M, N) (individual Head Start employees speculating that their exemption requests have “effectively,” Pls.’ Ex. L, N, been denied by a Head Start agency), *with United States v. Emerson*, 270 F.3d 203, 262 (5th Cir. 2001) (“There must be a *likelihood* that irreparable harm will occur. . . . [A] preliminary injunction will not be issued simply to prevent the possibility of some remote future injury.” (quoting 9 Wright, Miller & Kane, *Federal Practice & Procedure: Civil 2D* § 2948.1 (3d ed.))). And being required to wear a mask does not constitute irreparable harm, *Klaassen v. Trs. of Ind. Univ.*, ---F. Supp. 3d---, 2021 WL 3073926, at \*42 (N.D. Ind. July 18, 2021), as Plaintiffs apparently believe, PI Br. 24 (citing Pls.’ Ex. T).

The cases that Plaintiffs cite are not to the contrary. For example, *Planned Parenthood of Greater Texas Surgical Health Servs. v. Abbott*, 734 F.3d 406 (5th Cir. 2013), and *Veasey v. Abbott*, 870 F.3d 387, 390 (5th Cir. 2017) (cited at PI Br. 25), were cases in which a state law was enjoined by a court order, and the appellate courts noted the noncontroversial conclusion that “[w]hen a statute is enjoined, the State necessarily suffers the irreparable harm of denying the public interest in the enforcement of its laws.” *Planned Parenthood*, 734 F.3d at 419. And in *Texas v. United States*, 787 F.3d 733 (5th Cir. 2015), the court referred to a state forced to choose between incurring costs and changing its legal regime, *id.* at 752—here the states do not identify a similar pressure on them to change their legal regimes or face costs, they simply note that federal law has preempted state law, which is not an irreparable harm. See *Florida v. Dep’t of Health & Hum. Servs.*, No. 21-cv-2722 (N.D. Fla. Dec. 1, 2021), Order at 6, ECF No. 18 (declining to find preemptive effect as causing irreparable harm because “it is not a federal mandate that *all* Florida citizens must be vaccinated”).

Finally, Plaintiffs seek to rely on the alleged denial of their procedural right to comment on the Rule. PI Br. 25. They cite no cases, however, supporting the proposition that such an injury would be *irreparable* absent emergency injunctive relief. APA cases asserting a lack of notice and comment frequently proceed in the ordinary course, without the extraordinary remedy of preliminary relief.

#### **IV. The Balance of Equities and Public Interest Overwhelmingly Favor Denying an Injunction.**

The third and fourth requirements for issuance of a preliminary injunction—the balance of harms and whether the requested injunction will disserve the public interest—“merge when the Government is the opposing party.” *Nken v. Holder*, 556 U.S. 418, 435 (2009). Here, these considerations tilt decisively in the Government’s favor.

In discussing the public interest prong, Plaintiffs remarkably refuse to acknowledge the unparalleled American casualties from COVID-19. Contrary to Plaintiffs’ argument that the “only” harm from enjoining the Rule would be a “wait,” PI Br. 25, an injunction would harm the public

interest in slowing the spread of COVID-19 among young children in the Head Start program and those who come into close contact with them. See *In re MCP No. 165*, 2021 WL 5989357, at \*19 (noting that the “costs of delaying implementation” of a COVID-19 vaccine requirement are “comparatively high”). In the context of this pandemic, “federal courts across the country have routinely concluded that undoing orders deemed necessary by public health officials and experts to contain a contagious and fast-spreading disease would result in comparatively more severe injury to the community.” *Chambless Enters., LLC v. Redfield*, 508 F. Supp. 3d 101, 123 (W.D. La. 2020) (citation omitted). Accordingly, numerous courts reviewing “executive action designed to slow the spread of COVID-19” have concluded that “[t]he public interest in protecting human life—particularly in the face of a global and unpredictable pandemic—would not be served by” an injunction. *Tigges v. Northam*, 473 F. Supp. 3d 559, 573–74 (E.D. Va. 2020); see also, e.g., *Donovan v. Vance*, No. --- F. Supp. 3d ---, 2021 WL 5979250 at 7–8 (E.D. Wash. Dec. 17, 2021); *Wise v. Inslee*, No. 2:21-cv-0288, 2021 WL 4951571, at \*6 (E.D. Wash. Oct. 25, 2021); *Williams v. Brown*, ---F. Supp. 3d---, 2021 WL 4894264, at \*10–11 (D. Or. Oct. 19, 2021); *Johnson v. Brown*, ---F. Supp. 3d---, 2021 WL 4846060, at \*26–27 (D. Or. Oct. 18, 2021); *Mass Corr. Officers Federated Union v. Baker*, ---F. Supp. 3d---, 2021 WL 4822154, at \*7–8 (D. Mass. Oct. 15, 2021); *Valdez v. Grisham*, ---F. Supp. 3d---, 2021 WL 4145746, at \*13 (D.N.M. Sept. 13, 2021), *appeal filed*, No. 21-2105 (10th Cir. Sept. 15, 2021); *Harris v. Univ. of Mass., Lowell*, ---F. Supp. 3d---, 2021 WL 3848012, at \*8 (D. Mass. Aug. 27, 2021), *appeal filed*, No. 21-1770 (1st Cir. Sept. 28, 2021); *Am.’s Frontline Drs. v. Wilcox*, No. EDCV 21-1243, 2021 WL 4546923, at \*8 (C.D. Cal. July 30, 2021); *TJM 64, Inc. v. Harris*, 475 F. Supp. 3d 828, 840–41 (W.D. Tenn. 2020); *Talleywhacker, Inc. v. Cooper*, 465 F. Supp. 3d 523, 543 (E.D.N.C. 2020). By comparison, any theoretical harm to Plaintiffs, which, as explained above, is not irreparable and is purely speculative, “pales in comparison to the significant loss of lives that Defendants have demonstrated could occur” if the Rule is enjoined. *Chambless Enters.*, 508 F. Supp. 3d at 123 (citation omitted).

Moreover, “there is inherent harm to an agency in preventing it from enforcing regulations that Congress found it in the public interest to direct that agency to develop.” *Cornish v. Dudas*, 540 F. Supp. 2d 61, 65 (D.D.C. 2008), *aff’d*, *Cornish v. Doll*, 330 F. App’x 919 (Fed. Cir. 2009). Congress has charged the Secretary with the responsibility to protect the health and safety of children participating in the Head Start programs. *See* 42 U.S.C § 9831(2); *id.* § 9836a(a)(1). The public interest favors allowing the Secretary to fulfill these responsibilities.

## **V. Any Injunctive Relief Should Be Appropriately Limited.**

If the Court disagrees with Defendants’ arguments, any relief should be no broader than necessary to remedy any demonstrated irreparable harms of the specific Plaintiffs in this case. “A plaintiff’s remedy must be tailored to redress the plaintiff’s particular injury,” *Gill v. Whitford*, 138 S. Ct. 1916, 1934 (2018), and “injunctive relief should be no more burdensome to the defendant than necessary to provide complete relief to the plaintiffs,” *Madsen v. Women’s Health Ctr., Inc.*, 512 U.S. 753, 765 (1994) (citation omitted). Any relief should be limited in two respects.

First, any injunction should apply only to those aspects of the Rule for which the Court finds Plaintiffs have met their burden under the four-factor test for emergency relief. The Supreme Court has held a regulation severable where severance would “not impair the function of the statute as a whole, and there is no indication that the regulation would not have been passed but for its inclusion.” *K Mart Corp. v. Cartier, Inc.*, 486 U.S. 281, 294 (1988) (invalidating only the provision of a regulation that exceeded the agency’s statutory authority). Severability clauses, such as the one in the Rule, *see* 86 Fed. Reg. at 68,060, create a presumption that the validity of the entire regulation is not dependent on the validity of any specific unlawful provision if that unlawful provision would not impair the function of the regulation as a whole. *Alaska Airlines, Inc. v. Brock*, 480 U.S. 678, 686 (1987).

Second, as discussed above, *see supra* Part I, Plaintiffs lack standing because they do not operate any Head Start programs and are not recipients of any Head Start grants under 42 U.S.C. § 9836 or § 9840a. But, if the Court disagrees and concludes that some Plaintiffs do have standing, any

injunctive relief should be limited, at most, to the specific grants or programs operated by Plaintiffs that the Court identifies. “The Court’s constitutionally prescribed role is to vindicate the individual rights of the people appearing before it.” *Gill*, 138 S. Ct. at 1933; *see also id.* at 1934 (citing *Daimler Chrysler Corp. v. Cuno*, 547 U.S. 332, 353 (2006)); *Madsen*, 512 U.S. at 765. Plaintiffs here do not request a nationwide injunction in either their motion for a preliminary injunction or their motion for a temporary restraining order, and do not in fact even reference the scope of the relief they seek in either. This makes sense: Plaintiffs have no interest in whether Head Start programs in other States or operated by other grantees are subject to the Rule during the pendency of this lawsuit nor standing to assert claims on behalf of programs that Plaintiffs do not operate. Plaintiffs’ claims would be fully redressed through a preliminary injunction prohibiting the Secretary from “implementing” or “enforcing” the Rule against only those programs that Plaintiffs themselves operate.

Nationwide relief would be particularly harmful here given that the only Plaintiffs in this action are the specific plaintiff states and two other district courts are already considering similar challenges to the Rule as of the date of this filing. *See Brick v. Biden*, No. 2:21-cv-4386 (W.D. La. Dec. 22, 2021); *Texas v. Becerra*, No. 5:21-cv-300 (N.D. Tex. Dec. 10, 2021). A nationwide injunction would render any forthcoming order by the district courts in *Texas* and *Brick*, as well as any additional orders that might follow from other courts that might consider similar claims, meaningless as a practical matter. Moreover, nationwide injunctions “take a toll on the federal court system—preventing legal questions from percolating through the federal courts, encouraging forum shopping, and making every case a national emergency for the courts and for the Executive Branch.” *Trump v. Hawaii*, 138 S. Ct. 2392, 2425 (2018) (Thomas, J., concurring); *see also Holland v. Nat’l Mining Ass’n*, 309 F.3d 808, 815 (D.C. Cir. 2002) (“Allowing one circuit’s statutory interpretation to foreclose . . . review of the question in another circuit” would “squench the circuit disagreements that can lead to Supreme Court review.”). Consistent with those equitable principles, the Fifth Circuit has repeatedly vacated or stayed universal injunctions that apply to nonparties, including in a recently decided matter with respect to another



HHS vaccination requirement for CMS. *See Louisiana*, 2021 WL 5913302, at \*2 (“This vaccine rule is an issue of great significance currently being litigated throughout the country. Its ultimate resolution will benefit from ‘the airing of competing views’ in our sister circuits.”) (citation omitted); *see also Texas v. United States*, 14 F.4th 332, 341 (5th Cir. 2021); *Marshall v. Goodyear Tire & Rubber Co.*, 554 F.2d 730, 735 (5th Cir. 1977). There is no reason why Plaintiffs’ disagreement with the Rule should govern the rest of the country, portions of which undoubtedly welcome it as a lawful lifesaving measure.

### CONCLUSION

For the foregoing reasons, Plaintiffs’ Motions should be denied.

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Respectfully submitted,

BRIAN M. BOYNTON  
Acting Assistant Attorney General

MICHELLE R. BENNETT  
Assistant Branch Director  
Federal Programs Branch

/s/ Michael P. Clendenen  
MICHAEL P. CLENDENEN (DC Bar No. 1660091)  
CHRISTOPHER EDELMAN (DC Bar No. 1033486)  
MADELINE M. MCMAHON (DC Bar No. 1720813)  
MARCIA K. SOWLES (DC Bar No. 369455)  
Trial Attorneys  
U.S. Department of Justice  
Civil Division, Federal Programs Branch  
1100 L Street N.W.  
Washington, DC 20005  
Phone: (202) 305-8659  
Fax: (202) 616-8460  
christopher.edelman@usdoj.gov

*Attorneys for Defendants*